

Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities

**Fiscal Year End 2010
(July 2009-June 2010)**

**Prepared for
Department of Human Services
By Goold Health Systems**

**Submitted by
Pamela Smith, R.Ph., Project Coordinator
Iowa Medicaid Drug Utilization Review Commission**

October 1, 2010



STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
PATTY JUDGE, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
CHARLES KROGMEIER, DIRECTOR

September 27, 2010

Michael Marshall
Secretary of Senate
State Capitol
LOCAL

Mark Brandsgard
Chief Clerk of the House
State Capitol
LOCAL

Dear Mr. Marshall and Mr. Brandsgard:

Enclosed please find copies of reports to the General Assembly relative to the Iowa Medicaid Annual DUR Report.

These reports were prepared pursuant to the directive contained in Iowa Code 249A.24, subpart 3.

The Commission realized an overall direct cost savings of \$2.90 for every dollar spent on the program administratively. State money for this program is matched by the federal government at a 3 to 1 ratio (federal to state), so savings can also be stated as \$11.60 per state dollar spent. Total annualized cost savings estimates (\$785,066.40) were increased by approximately 30% when compared to state fiscal year ending 2009.

Savings from patient-focused reviews (\$103,577.16) decreased slightly compared to state fiscal year ending 2009. This decrease was most likely due to the fact that a large portion of suggestions are on duplicate therapy with mental health drugs, which typically do not result in a change in drug therapy. In addition, an evolving PDL that controls costs through cost effective medications and Prior Authorization (PA) resulted in fewer suggestions being made to providers. Savings from problem-focused reviews (\$681,489.24) increased by 83% (\$563,956.21) compared to state fiscal year ending 2009 due to an increase in the number of interventions sent to providers.

Sincerely

Jennifer Davis Harbison
Legislative Liaison

Enclosure

cc: Chester J. Culver, Governor
Legislative Service Agency
Kris Bell, Senate Majority Caucus
Peter Matthes, Senate Minority Caucus
Zeke Furlong, House Majority Caucus
Brad Trow, House Minority Caucus

TABLE OF CONTENTS

Background Information	Page 1
Overall Results	Page 4
Results by Review Type	Page 6

Appendix A	Commission Members
Appendix B	Evaluation Procedure
Appendix C	Overall Program Results
Appendix D	Results of Patient-Focused Reviews
Appendix E	Results of Problem-Focused Reviews
Appendix F	Descriptions of Problem-Focused Reviews
Appendix G	Prior Authorization Recommendations
Appendix H	Prospective Drug Utilization Review Recommendations
Appendix I	FUL
Appendix J	Newsletters
Appendix K	Web Site
Appendix L	Quarterly Management Reports
Appendix M	Meeting Minutes
Appendix N	Mental Health Advisory Group
Appendix O	Smoking Cessation Report
Appendix P	Recommendations to the P & T

The Iowa Medicaid Drug Utilization Review Commission

Goold Health Systems has developed the following report for the Iowa Department of Human Services. This report provides a summary description of the activities of the Iowa Medicaid Drug Utilization Review Commission, along with an evaluation of the Iowa Medicaid retrospective drug utilization review program. Information contained in this report covers projects completed and evaluated during the time period of July 2009 through June 2010.

Background Information

Established in 1984, the DUR Commission is charged with promoting the appropriate and cost-effective use of medications within the Iowa Medicaid member population. Acting as a professional advisory group, the Commission analyzes medication utilization by the members of Iowa Medicaid and performs educational initiatives to optimize member outcomes. The Commission performs retroDUR and educational outreach through patient-focused reviews and problem-focused reviews. The Commission supports the proDUR program through criteria review and acts as a resource to the DHS on other issues concerning appropriate medication use.

Patient-Focused Reviews

Patient-focused reviews are completed with the review of 300 member profiles at each meeting (eight times annually). The DUR subcontractor generates these profiles through a complex screening process. The first step of the screening process subjects member profiles to a therapeutic criteria screen. If a profile is found to have failed one or more therapeutic criteria, the member profiles are then assigned a level of risk based on their medication history and potential for adverse events regarding medication. The profiles with the highest level of risk are then selected for the Commission to review. Six months of prescription claims data and medical claims data, if available, are assessed to determine this risk factor.

The member profiles selected from this process are manually reviewed by the Commission to minimize false positives generated by the computer selection process. The Commission identifies situations where educational intervention might be appropriate. Through these interventions, suggestions regarding medication therapy are communicated to the care providers. Templates are developed for suggestions that are frequently communicated to providers. The reviewer may also author an individualized suggestion if a template suggestion is not applicable. These template suggestions are located in the tab labeled Therapeutic Recommendations.

Educational interventions are generally done by letters to prescribers and pharmacists, but may also be done by telephone or in person. The suggestions made by the Commission are educational and informative in nature. Suggestions may be classified as either therapeutic or cost saving in nature. In addition, these suggestions are classified by problem identified for reporting purposes. The classifications are as follows:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration
- Unnecessary Drug Use
- Therapeutic Duplication
- High Cost Drug

- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy
- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Suggestions are intended to promote appropriate and cost-effective use of medications. When suggestions result in cost savings, these savings are calculated based on decreased cost of medications. However, several of these classes of interventions are intended to increase the use of medications. Examples are member underuse and missing drug therapy. In these cases, the addition of medication therapy will increase medication expenditures, but will be beneficial to the member and should result in cost savings in medical services and/or improved quality of life. Cost savings in these situations cannot be calculated due to data limitations. Therefore, these suggestions are considered to have a positive impact on the program with no medication cost savings. Cost savings on medical services are assumed however not calculated.

Providers are invited to respond to the Commissions' suggestions and to request additional information from the Commission. Responses are voluntary and response rates are calculated for prescribers and pharmacists.

Once a member's profile is reviewed, it is excluded from the selection process for nine months to eliminate repeat selections. After this waiting period, the current profile for each member is generated and reviewed to determine if the Commission's suggestion was implemented. If so, fiscal considerations resulting from that change are also calculated. The policy regarding these calculations is included in Appendix B.

Problem-Focused Reviews

Problem-focused reviews narrow the emphasis of review to a specific issue that has been determined to be an area where a targeted educational effort to providers may be valuable. Topics for review are selected from findings of patient-focused reviews or from reviews of medical literature. Criteria are developed to identify the members who may benefit from intervention and educational materials are disseminated to their providers. Providers are encouraged to voluntarily respond. The member profile is generated again in an appropriate amount of time (typically 6 to 9 months) to determine the impact rate of the intervention, along with any fiscal considerations. The policy regarding these calculations is also included in Appendix B.

Administrative Review

The Commission will review utilization data and medical literature to make recommendations to the Department of Human Services (DHS) regarding policy issues. These recommendations are made to promote the appropriate use of medications and positive member outcomes. Recommendations are made at the request of the DHS or at the Commission's discretion. All authority to accept or reject DUR Commission recommendations lies with the DHS. The Commission may make recommendations but does not make policy. Primary areas for recommendations include proDUR, drug prior authorization (PA), coverage of medications, and administrative and billing procedures. The prospective drug utilization review (proDUR) system is currently administered by Goold Health Systems (GHS) and was implemented statewide in July 1997. The Commission reviews the criteria utilized by GHS and provides input regarding therapeutic validity. Special attention is given to eliminating false positive messaging.

The Commission recommends new or updated guidelines for use in the drug prior authorization program. This process is based on reviews of medical literature in addition to comparisons with other public and private sector programs. Input from providers outside the Commission, particularly specialists, is often sought when developing these guidelines. Once developed, the guidelines are sent to the medical and pharmacy associations in the state for comments. After considering these comments, a final recommendation is made to the Department. The Department may or may not accept the recommendation or may alter the recommendation. These guidelines are then subject to the administrative rules process prior to any policy implementation.

The Commission also makes recommendations regarding coverage of medication or devices. As most coverage requirements are defined by OBRA '90, these recommendations generally encourage coverage of optional services. An example would be the coverage of select over-the-counter medications. If the Department accepts the Commission's recommendation, the proposed coverage change is subject to the administrative rules process prior to implementation.

The Commission reviews pharmacy claims with respect to administrative procedures. Situations where funding for medication can be obtained from other sources are relayed to the Department for their action. For instance, Medicare will pay for immunosuppressive medications for transplant patients and nebulizer solution for dual eligible patients. The Commission also identifies situations where the Department may recover funds from inappropriate billing.

Overall Results

Activities of the Commission were evaluated during the fiscal year ending 2010 for interventions performed in the previous or the current fiscal year. The direct cost savings from all activities of the Commission are calculated to be \$785,066.40* which equates to \$2.90* for every \$1.00 of combined federal and state dollars spent administratively. This calculation is based on estimates regarding two types of reviews: patient-focused reviews and problem-focused reviews. These results are also found in Appendix C.

Cost Savings Estimate	\$785,066.40*
Cost of the Program (state and federal dollars)	\$270,000.00
Net cost Savings Estimate	\$515,066.40*
Savings per Total Dollar Spent (state and federal)	\$2.90*
Savings per State Dollar Spent	\$5.82*

Patient-focused reviews resulted in \$103,577.16* in direct cost savings, or \$119.05* per patient evaluated. This estimate is based on the 1,252 suggestions made by the Commission identified from the review of the medication therapy of 2,400 patients. Of these 1,252 suggestions, 119 suggestions were implemented by the providers, resulting in a 9.50% impact rate.

Patient-Focused Profile Review	
Suggestions Made	1,252
Therapy Changed	119
IMPACT RATE	9.50%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	\$119.05*
Dollars Saved on Medication	\$103,577.16*

Problem-focused reviews resulted in an estimated cost savings of \$681,489.24* or \$419.38 saved per patient evaluated. This estimate is based on the review of profiles with 1,625 patients selected for interventions. Therapy was changed for 567 patients, resulting in an impact rate of 34.89%.

Problem-Focused Profile Review	
Patients Evaluated	1,625
Therapy Changed	567
IMPACT RATE	34.89%
Cost Savings Estimates:	
Dollars Saved on Patient Reviews	\$681,489.21*
Dollars Saved per Patient Evaluated	\$419.38*
Total Dollars Saved on Medication	\$681,489.21*

Comparison to Previous Reports

Cost savings estimates for State FYE 2010 (\$785,066.40*) are higher than last year. However, in comparison to previous years, the cost savings estimates are lower. This decrease is due in part to the following:

- An evolving Preferred Drug List (PDL) that controls costs through Prior Authorization (PA) and the use of preferred medications that are cost effective for the State which resulted in fewer suggestions being made to providers.
- A majority of cost savings opportunities that had been included in past annual reports are no longer available such as quantity limits, dose consolidation, and age edits as these were implemented as ProDUR edits for the pharmacy program.

The savings from State FYE 2010 patient-focused reviews (\$103,577.16*) were lower than State FYE 2009 (\$114,357.25*). The number of suggestions made (1,252) vs. (407) increased while the number of suggestions that were accepted (119) vs. (193) decreased from State FYE 2009. These decreases in the number of suggestions that were accepted are largely due to the fact that a large number of suggestions made are related to duplicate therapy of mental health drugs, which usually do not result in a change in drug therapy.

The savings from problem-focused reviews for State FYE 2010 (\$681,489.24*) were higher than State FYE 2009 (\$117,533.03*). This was due to the fact that in State FYE 2010, there were eight total problem focused studies evaluated versus five problem focused studies in State FYE 2009.

Results by Review Type

Patient-Focused Review

During this evaluation period, 2,515 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 1,252 letters (49.78%) were mailed to prescribers, and 1,263 (50.22%) letters were mailed to pharmacies. Providers are invited to voluntarily respond to Commission letters. Providers returned 943 responses to these letters, resulting in an overall response rate by the providers of 75.32%. Of this total, 557 (59.07%) responses were from prescribers and 386 (49.03%) were from pharmacies. The response rate differed between physicians and pharmacies; 45% for physicians and 31% for pharmacies.

In these 2,515 educational letters, the Commission made 1,252 suggestions. Of these suggestions, 1,214 (96.96%) were therapeutic in nature while 38 (3.04%) were cost-saving in nature. The suggested change was implemented in 119 cases, resulting in an overall impact rate of 9.50%. Of these changes, 112 (94.12%) were therapeutic in nature while 7 (5.88%) were cost-saving in nature.

Of the 1,252 suggestions, four types of suggestions accounted for over 90.26% of the total. Those four suggestions were Drug-Drug Interaction (4.18%), Patient Overuse (3.04%), Therapeutic Duplication (80.19%), and Not Optimal Dose (4.15%). No other single category accounted for more than 3% of the total suggestions. Of the 119 changes, the most common reasons for the Commission's inquiry were Inappropriate Billing (5.04%), Therapeutic Duplication (76.47%), Not Optimal Dose (7.56%), and Drug-Drug Interaction (3.36%). No other single category accounted for more than 2.5% of the changes. Detailed information is found in Appendix D.

The suggestions that resulted in change the highest percentage of the time were Inappropriate Billing (15.49%), Therapeutic Alternative (23.83%), Missing Drug Therapy (17.39%), and Not Optimal Dose (17.39%).

Implementation of therapeutic suggestions resulted in direct drug cost savings of \$103,107.12*. Implementation of the cost-saving suggestions resulted in direct drug cost savings of \$470.04*. The total amount saved on medication utilization was calculated to be \$103,577.16* for the 870 patients evaluated, or \$119.05* per patient. The complete details of the results of patient-focused studies reported monthly are also outlined in Appendix D.

Included in Appendix D are Intervention Case Summary examples presented to the Commission during the year. These summaries detail the process of specific patient-focused reviews including problem identification, intervention, provider response and outcome. The examples provide an easily understood method to demonstrate the value of retrospective patient focused DUR.

* Savings reported are pre-rebate, total dollars

Problem-Focused Reviews

Eight problem-focused reviews were evaluated during the fiscal year. In conducting these studies, 1,625 patient profiles were reviewed and selected for intervention. Of these patients, 567 cases showed evidence of a positive outcome, resulting in an impact rate of 34.89%. These changes in therapy resulted in annualized cost savings of \$681,489.24 or \$419.38 per patient evaluated. Results of all focus studies are detailed in Appendix E. The purpose for each problem-focused review and a complete description of results are available in Appendix F.

Administrative Review

Prior Authorization

The Commission annually reviews the prior authorization program for clinical appropriateness. Changes are recommended to the Department of Human Services. During the State FYE 2010, the Commission reviewed all therapeutic categories requiring prior authorization as well as therapeutic criteria to support operations of the Preferred Drug List. Recommendations for modifications to existing criteria were made for the following categories: Ketorolac, Muscle Relaxants, Antihistamines, Smoking Cessation Therapy, Proton Pump Inhibitors, Biologicals for Ankylosing Spondylitis, and Biologicals for Arthritis. The following is a list for which new categories of clinical prior authorization criteria were developed: Thrombopoietin Receptor Agonists, Febuxostat (*Uloric*), Short Acting Narcotics, Dipeptidyl Peptidase-4 (DPP-4) Inhibitors, Lidocaine Patch, and Chronic Pain Syndromes. The recommendation was made to remove existing criteria for Ergotamine Derivatives due to low utilization of this category of drugs.

In addition, the Commission reviewed the new *Red Book Guidelines* on RSV prevention to determine if changes needed to be made to the Palivizumab (*Synagis*) Clinical PA criteria. They felt that the evidence supporting the new *Red Book Guidelines* contained no new clinical data. Therefore, the Commission recommended making no changes to the PA criteria for the 2009-2010 RSV Season. They went on to recommend a start date of November 15th with a maximum of 5 doses.

These recommendations can be found in Appendix G.

Prospective Drug Review

The Commission reviews and recommends prospective drug utilization review criteria to be utilized by the Department. The following prospective DUR edits were recommended to the Department by the Commission in State FYE 2009:

- Quantity Limit of 30 tablets per 30 days on *Uloric* 40mg tablets.
- Point of Sale age edit on *Nuvigil* to restrict use to members 17 years of age and older.
- Quantity Limit of 120 tablets per 180 days at a maximum dose of four tablets per day for carisoprodol when the criteria for coverage is met.

Information regarding the Commission recommendations for prospective DUR can be found in Appendix H.

Other Activities

The Commission reviews changes made to the state maximum allowable cost (SMAC) list and the federal upper limit (FUL) list for prescription drugs to determine if narrow therapeutic index concerns exist. Appendix I lists the changes to the SMAC and FUL programs that were reviewed by the Commission.

Three newsletters were written and distributed by the Commission to the Medicaid provider community during this fiscal year. A copy of these newsletters is provided in Appendix J. Topics include:

- Palivizumab (Synagis) PA Criteria 2009-2010 RSV Season
- Recommendation Regarding ECG Monitoring in Patients on Methadone by the CSAT
- Drugs for Dementia
- Anti-Acne Prior Authorization Criteria
- DUR Activities
- Diabetes News
- FDA Updates
- Health Reform Legislation

The Commission maintains a web site to improve communication with a variety of stakeholders. The web site is found at www.iadur.org. The site contains information regarding upcoming meeting dates, locations, agendas, minutes from the previous meeting, the Smoking Cessation Report to the State, as well as past issues of the provider newsletter, the *DUR DIGEST*. In addition the web site provides meeting agendas and minutes for the Drug Utilization Review Mental Health Advisory Group. A copy of this web site is found in Appendix K.

Dr. Casey Clor, M.D and Larry Ambroson, R.Ph. were selected to serve a four-year term and attended their first meeting in August 2009.

Bruce Alexander, R.Ph. completed his second term in June. Brett Faine, Pharm.D. was selected to serve a four-year term beginning July 1, 2010.

Quarterly management reports were developed to allow the Commission to analyze changes in medication use across the entire Medicaid patient population. Copies are found in Appendix L. Complete meeting minutes for all Commission meetings are available in Appendix M.

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG) was established in State FYE 2008. Descriptions of the program, as well as meeting minutes are found in Appendix N.

The Commission is responsible for monitoring the smoking cessation benefit provided under the medical assistance program and for providing a report of utilization, client success, cost effectiveness, and recommendations for any changes in the benefit to the State. This report is located in Appendix O.

Periodically the Commission will make recommendations to the Iowa Medicaid Pharmacy & Therapeutics Committee regarding the status of a medication on the Preferred Drug List (PDL). A copy of State FYE 2010 recommendations can be found in Appendix P.

Appendix A

Commission Members

**Iowa Medicaid Drug Utilization Review
Commission Members
2009-2010**

Bruce Alexander, R.Ph., Pharm.D., BCPP

Bruce Alexander was a clinical pharmacist specialist in the Departments of Pharmacy and Psychiatry at the Iowa City Veterans Affairs Medical Center for 33 years. He is currently a Mental Health Pharmacoepidemiologist for VISN 23 of the Veterans Health Administration. He is also a Professor Emeritus (Clinical) in the College of Pharmacy and Department of Psychiatry, College of Medicine, The University of Iowa. He graduated from Drake University College of Pharmacy and received his Doctor of Pharmacy degree from the University of Minnesota. He is board certified in Psychiatric Pharmacy. He has been active in the Iowa Pharmacy Association serving in the House of Delegates and on the Board of Trustees. His second term will expire in 2010.

Larry Ambrosen, R.Ph.

Larry Ambrosen currently owns and operates The Medicine Shoppe Pharmacy in Newton, Iowa. Before returning to Iowa, Larry worked as a staff pharmacist for Columbia Regional Hospital in Columbia, Missouri. In addition to running his business, Larry also sits on a review board with Capstone Health in Newton. Larry was appointed to the DUR Commission in 2009; his first term will expire in 2013.

Casey Clor, M.D.

Dr. Clor has been a family practice physician at the Mercy East Family Practice clinic since completing his residency at the Mercy/Mayo Family Practice Residency Program in Des Moines. Dr. Clor also holds a Masters of Pharmacy Sciences. In addition to family medicine, Dr. Clor has experience in emergency medicine, has served as the Assistant Director for the Mercy Center for Weight Reduction, as well as serving as part of the adjunct faculty for Des Moines University. He currently is serving on the Governor's Council on Physical Fitness and Nutrition. Dr. Clor was appointed to the DUR Commission in 2009; his first term will expire in 2013.

Mark Graber, M.D., FACEP

Dr. Graber is a Professor of Emergency Medicine and Family Medicine at the University of Iowa Carver College of Medicine. Dr. Graber graduated from Eastern Virginia Medical School and completed his Family Practice Residency at the University of Iowa. In addition to his clinical duties, Dr. Graber serves as an advisor to medical students and residents, and has published numerous text books, reviews, and papers in publications such as *The Annals of Pharmacotherapy*, *Emergency Medicine*, and *American Family Physician*. Dr. Graber also serves as an associate Clinical Editor of the Prescribers Letter. Through his travels, Dr. Graber has presented throughout the United States as well as Ukraine, Russia, and China. In 2007, Dr. Graber was honored by appearing on the "Best Doctors In America" list. Dr. Graber was appointed to the Commission in 2008; his term will expire in 2012.

Craig Logemann, R.Ph., Pharm.D., BCPS, CDE

Craig Logemann is a clinic pharmacist with Partners in Health Clinics in Des Moines. He graduated with his Bachelor Degree in Pharmacy from the University of Iowa in 1988. He completed a pharmacy residency at the University of Iowa Hospitals and Clinics. Later, he received his Doctor of Pharmacy degree from the University of Minnesota. He was an Assistant Professor at the University of Iowa College of Pharmacy for nine years prior to accepting his current position. His term will expire in 2012.

Susan Parker, Pharm.D.

Susan Parker is the Pharmacy Consultant in the Bureau of Long Term Care for the Department of Human Services and serves as liaison to the Commission. She graduated with a Doctor of Pharmacy degree from Mercer Southern School of Pharmacy in Atlanta, Georgia. She is also a graduate of Gannon University in Erie, Pennsylvania with a Bachelor of Science degree Physician Assistant. Dr. Parker brings to the Commission a variety of experience in health care as an Iowa Medicaid drug prior authorization pharmacist, community pharmacist, and physician assistant. She is a member of the American Medicaid Pharmacy Administrators Association and the Western Medicaid Pharmacy Administrators Association.

Laurie Pestel, Pharm,D

Laurie Pestel is the pharmacy manager at Hy-Vee in Red Oak, Iowa. She graduated with her Doctor of Pharmacy degree from Creighton University in 2000. She served on the Board of Professional Affairs as a member of the Iowa Pharmacy Association in 2006. Laurie has experience with both long-term care and retail pharmacy. Her term will expire in 2011.

Richard Rinehart, M.D.

Dr. Rinehart is a staff psychiatrist at the Iowa City VA Medical Center and a clinical assistant professor at the University of Iowa Hospital and Clinics. He graduated from Ohio State University and completed his residency at the University of Iowa. He was in private practice in Cedar Rapids for 12 years prior to accepting his current position. He is a member of the Iowa Psychiatric Society. Dr. Rinehart's second term will expire in 2011.

Sara Schutte-Schenck, D.O.

Dr. Schutte is a graduate of Drake University and the University of Osteopathic Medicine and Health Sciences. She completed her pediatric residency at Blank Children's Hospital and is currently in practice in Des Moines. Dr. Schutte is board certified by the American Academy of Pediatrics. She has previously served on P & T committees as well as credentialing committees for Securecare of Iowa. Currently, she serves as a member of the Utilization Management Committee for Coventry Healthcare of Iowa. Dr. Schutte's term will expire in 2012.

Appendix B

Evaluation Procedure

EVALUATION OF THE IMPACT OF PROSPECTIVE AND RETROSPECTIVE DRUG UTILIZATION REVIEW INTERVENTIONS

The goal of Drug Utilization Review (DUR) is to evaluate cost savings and provide quality assurance of medication use. The DUR Commission works in conjunction with the pharmacy medical program at the Iowa Medicaid Enterprise to contribute to the overall success of the program. The Drug Utilization program:

- Evaluates three areas of activity including Patient-focused Drug Utilization Reviews, Problem-focused Drug Utilization Reviews, and Administrative Activities.
- Examines only direct drug costs. DUR evaluation does not have the ability to quantify its impact on other health services such as hospitalizations, ER visits, and physician visits.
- Reports pre-rebate savings since access to supplemental rebates is not within the scope of the DUR program.
- Often provides recommendations that are qualitative, such as improved health outcomes, rather than quantitative in nature.

As a general principle, evaluations are based upon an observed change in the targeted prescribing or dispensing pattern, as well as changes seen in therapy of the individual patients. One evaluation approach is to observe and quantify changes in prescribing due to a given intervention compared to a control group of providers who do not receive the intervention. The intervention's impact on prescribing may be more readily detectable by this method and could be measured by comparing the two groups of patients or prescribers. However, it is very difficult to design a scientifically sound control group given the many variables surrounding patient care. Therefore, in most instances the DUR Commission has chosen to forego use of a control group to achieve the greatest impact. Although the evaluation of the intervention may be less scientific, intervention on behalf of all the patients is more desirable. In this instance, prescribing trends may not be available for comparison, but savings and benefit can still be quantified at the individual patient level.

Patient-focused DUR

Patient-focused DUR concentrates efforts on specific suggestions made about an individual patient. Each suggestion, or template, attempts to make a change in therapy. These changes are either therapeutic or cost-saving in nature; however, these situations are not necessarily mutually exclusive. A therapeutic change – one that improves the patient's therapy in some way – may also produce cost savings. Cost-saving changes are attempted when a patient is not receiving a medication in the most economical form. The intervention does not change the medication but points out that the same medication could be given in a more cost-effective manner. Each template and intervention is evaluated to determine if the proposed change was implemented and, if so, what economic implications can be calculated.

All savings for patient-focused review are based on annualized savings for one year only. Reporting on patient-focused interventions will provide the following information:

- Total number of templates mentioned
- Number of templates that were therapeutic in nature
- Number of templates that were cost-saving in nature
- Total number of changes implemented
- Number of changes that were therapeutic in nature
- Number of changes with positive impact without savings
- Number of changes that were cost-saving in nature
- Total dollars saved from therapeutic changes
- Total dollars saved from cost-saving changes
- Total dollars saved
- Impact of interventions expressed as a percentage

All templates are described by one of sixteen classifications. These classifications indicate the general type of intervention addressed by the template. Reports will also include a breakdown by classification (therapeutic or cost-saving) of the templates used in the patient-focused letters. This data will show which templates are cited most often, result in change most often, and result in higher cost savings.

Templates that are therapeutic in nature include:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration of Use
- Unnecessary Drug Use
- Therapeutic Duplication
- High Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy

Templates that are cost saving in nature include:

- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

recommending step therapy for appropriate drug use.

Example: The DUR Commission developed the criteria for the Nicotine Replacement Therapy prior authorization.

Prior Authorization is required for over-the-counter nicotine replacement patches and nicotine gum. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment in the Quitline Iowa counseling program is required for approval.
- 3) Approvals will only be granted for patients eighteen years of age and older.
- 4) The maximum allowed duration of therapy is twelve weeks within a twelve-month period.
- 5) A maximum quantity of 14 nicotine replacement patches and/or 110 pieces of nicotine gum may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and/or 330 pieces of nicotine gum. Following the first 28 days of therapy, continuation is available only with documentation of ongoing participation in the Quitline Iowa program.

- Preferred Drug List (PDL)

Definition: A list comprised of drugs recommended to the Iowa Department of Human Services by the Iowa Medicaid Pharmaceutical and Therapeutics Committee that have been identified as being therapeutically equivalent within a drug class and that provide cost benefit to the Medicaid program.

Impact: The DUR Commission makes referrals to and considers requests from the Pharmacy and Therapeutics (P&T) Committee to improve drug therapy.

Example: The DUR Commission recommended that the Iowa Medicaid Pharmacy and Therapeutics Committee change the status of products containing carisoprodol on the PDL from preferred to nonpreferred.

- Disease management

Definition: A coordinated process by which Iowa Medicaid identifies and treats diseases within defined patient populations. This goal is achieved by identifying and delivering the most effective and efficient combination of available resources.

Impact: The Commission reviews disease state guidelines to determine appropriate drug use, shares drug utilization information, and makes recommendations to improve therapeutic outcomes.

Example: DUR exchanged patient specific information with case management regarding utilization patterns of Advair®.

Appendix C

Overall Programs Results

**Program Evaluation/Cost Savings Estimates
Iowa Medicaid Retrospective Drug Utilization Review
Annual Report
State Fiscal Year 2010**

Patient Focused Profile Review

Suggestions Made	1,252
Therapy Changed	119
Impact Rate	9.50%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	\$119.05
Dollars Saved on Medication	\$103,577.16

Problem-Focused Profile Review

Suggestions Made	1,625
Therapy Changed	567
Impact Rate	34.89%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	\$419.38
Dollars Saved on Medication	\$681,489.24

Cost Savings Estimate	\$785,066.40
Cost of the Program (State & Federal)	\$270,000.00
Net Cost Savings Estimate	\$515,066.40

Savings Per Dollar Spent (State and Federal)	\$2.90
---	---------------

Savings Per State Dollar Spent	\$5.82
---------------------------------------	---------------

Appendix D

Results Patient-Focused

Patient - Focus
State FYE 2010

Reviews

Initial Review Date

October 2008 - September 2009

Re-review Date

July 2009 - June 2010

Patient Profiles Reviewed 2,400
Profiles Available for Evaluation 870

Intervention Letters Sent

Prescribers	1,252	49.78%
Pharmacists	1,263	50.22%
Total	2,515	

Responses Received

Prescribers	557	59.07%	Overall Response Rate	75.32%
Pharmacists	386	49.03%	Prescriber Response Rate	44.49%
Total	943	100.00%	Pharmacy Response Rate	30.56%

Total Number of Suggestions

Therapeutic	1,214	96.96%
Cost-Saving	38	3.04%
Total	1,252	

Total Number of Changes

Therapeutic	112	94.12%	Impact Rate	9.50%
Cost-Saving	7	5.88%		
Positive Impact Only	0	0.00%		
Total	119			

Patient - Focused Review
Month by Month Breakdown
State FYE 2010

Initial Review Date Evaluation Date	Nov-08 Aug-09	Dec-08 Sep-09	Feb-09 Nov-09	Mar-09 Dec-09	May-09 Feb-10	Jun-09 Mar-10	Aug-09 May-10	Sep-09 Jun-10	Total
Profiles Reviewed	300	300	300	300	300	300	300	300	2,400
Profiles Available for Evaluation	149	114	99	83	123	92	110	100	870
Total Number of Suggstions Made	237	169	144	119	173	126	158	126	1,252
Therapeutic	237	166	143	118	166	120	145	119	1,214
Cost Saving	0	3	1	1	7	6	13	7	38
Total Number of Changes Made	13	24	13	9	18	13	19	10	119
Therapeutic	13	23	13	9	18	12	15	9	112
Cost Saving	0	1	0	0	0	1	4	1	7
Positive Impact Only	0	0	0	0	0	0	0	0	0
Total Dollars Saved - Therapeutic	\$12,238.68	\$31,160.04	\$5,043.48	\$7,130.88	\$19,262.40	\$10,617.00	\$8,427.24	\$9,227.40	\$103,107.12
Total Dollars Saved - Cost Saving	\$0.00	\$470.04	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$470.04
Total Dollars Saved on Medication*	\$12,238.68	\$31,630.08	\$5,043.48	\$7,130.88	\$19,262.40	\$10,617.00	\$8,427.24	\$9,227.40	\$103,577.16
Total Dollars Saved per Profile	\$82.14	\$277.46	\$50.94	\$85.91	\$156.60	\$115.40	\$76.61	\$92.27	\$119.05

**Medicaid DUR Impact Assessment
Report
Patient-Focused Reviews
State FYE 2010**

Initial Review Date Evaluation Date	Nov-08 Aug-09	Dec-08 Sep-09	Feb-09 Nov-09	Mar-09 Dec-09	May-09 Feb-10	Jun-09 Mar-10	Aug-09 May-10	Sep-09 Jun-10	Total	
Profiles Reviewed	300	300	300	300	300	300	300	300	2,400	
Profiles Evaluated	149	114	99	83	123	92	110	100	870	
Letters Sent	475	339	288	240	347	254	319	253	2,515	100.00%
Prescribers	237	169	144	119	173	126	158	126	1,252	49.78%
Pharmacy	238	170	144	121	174	128	161	127	1,263	50.22%
Responses Received	132	138	108	81	124	103	156	101	943	100.00%
Prescribers	83	75	72	48	75	63	82	59	557	59.07%
Pharmacy	49	63	36	33	49	40	74	42	386	40.93%
Total Number of Templates Mentioned	237	169	144	119	173	126	158	126	1,252	100.00%
Therapeutic	237	166	143	118	166	120	145	119	1,214	96.96%
Cost-Saving	0	3	1	1	7	6	13	7	38	3.04%
Total Number of Changes Made	13	24	13	9	18	13	19	10	119	100.00%
Therapeutic	13	23	13	9	18	12	15	9	112	94.12%
Cost-Saving	0	1	0	0	0	1	4	1	7	5.88%
Positive Impact Only	0	0	0	0	0	0	0	0	0	0.00%
Total Dollars Saved - Therapeutic Changes	\$12,238.68	\$31,160.04	\$5,043.48	\$7,130.88	\$19,262.40	\$10,617.00	\$8,427.24	\$9,227.40	\$103,107.12	99.55%
Total Dollars Saved - Cost Saving Changes	\$0.00	\$470.04	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$470.04	0.45%
Total Dollars Saved on Medication*	\$12,238.68	\$31,630.08	\$5,043.48	\$7,130.88	\$19,262.40	\$10,617.00	\$8,427.24	\$9,227.40	\$103,577.16	100.00%
Total Dollars Saved Per Profile Evaluated	\$82.14	\$277.46	\$50.94	\$85.91	\$156.60	\$115.40	\$76.61	\$92.27	\$119.05	

*Savings reported are pre-rebate, total dollars

Comment Type
Patient Focused Reviews
State FYE 2010

Initial Review Date Evaluation Date	Nov-08 Aug-09	Dec-08 Sep-09	Feb-09 Nov-09	Mar-09 Dec-09	May-09 Feb-10	Jun-09 Mar-10	Aug-09 May-10	Sep-09 Jun-10	Total	
Template Classification	Suggestions	Changes	Suggestions	Changes	Suggestions	Changes	Suggestions	Changes	Total Suggestions	Total Changes
Drug-Disease Interaction	0	0	0	0	0	0	1	0	1	0
Drug-Drug Interaction	7	5	3	1	4	0	3	0	11	2
Drug-Gender Alert	0	0	0	0	0	0	0	0	1	0
Inappropriate Billing	0	2	1	0	0	2	0	4	1	10
Missing Drug Therapy	0	1	0	0	0	1	0	0	0	0
Not Optimal Dosage Form	0	1	1	0	1	0	4	0	3	1
Not Optimal Dose	15	1	2	2	0	7	1	6	2	4
Not Optimal Drug	13	5	1	2	0	4	0	2	0	3
Not Optimal Duration	7	1	4	0	0	0	5	1	3	0
Patient Overuse	11	7	0	7	1	3	0	2	0	8
Potential Generic Use	0	0	0	0	0	0	1	0	0	0
Therapeutic Alternative	1	0	0	0	0	0	1	1	0	0
Therapeutic Duplication	180	11	132	18	125	11	100	8	146	14
Unnecessary Drug Therapy	3	0	0	0	0	0	0	0	1	0
Total	237	13	169	24	144	13	119	9	173	18
									126	13
									158	19
									126	10
									1	0
									5	0
									1,252	119

**Patient Focused Reviews
State FYE 2010**

Template Classification	Total Suggestions	Total Changes	% of Total Suggestions	% of Total Changes	% of Suggestions Changed	% Dollars Saved
Drug-Disease Interaction	1	0	0.08%	0.00%	0.00%	0.00%
Drug-Drug Interaction	36	4	2.88%	3.36%	8.52%	0.05%
Drug-Gender Alert	3	0	0.24%	0.00%	0.00%	0.00%
Inappropriate Billing	22	6	1.76%	5.04%	15.49%	0.51%
Missing Drug Therapy	4	1	0.32%	0.84%	11.92%	0.00%
Not Optimal Dosage Form	15	1	1.20%	0.84%	3.97%	0.00%
Not Optimal Dose	52	9	4.15%	7.56%	17.39%	2.85%
Not Optimal Drug	34	1	2.72%	0.84%	2.38%	2.07%
Not Optimal Duration	34	3	2.72%	2.52%	6.07%	0.00%
Patient Overuse	38	1	3.04%	0.84%	1.70%	0.00%
Potential Generic Use	1	0	0.08%	0.00%	0.00%	0.00%
Therapeutic Alternative	3	2	0.24%	1.68%	23.83%	7.12%
Therapeutic Duplication	1,004	91	80.19%	76.47%	8.71%	87.40%
Unnecessary Drug Therapy	5	0	0.40%	0.00%	0.00%	0.00%
Total	1,252	119	100.00%	100.00%	9.50%	100.00%

Savings By Template Class

State FYE 2010

Initial Review Date Evaluation Dte	Nov-08 Aug-09	Dec-08 Sep-09	Feb-09 Nov-09	Mar-09 Dec-09	May-09 Feb-10	Jun-09 Mar-10	Aug-09 May-10	Sep-09 Jun-10	Total
<u>Template Classification</u>									
Drug-Disease Interaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Drug-Drug Interaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$48.72	\$0.00	\$48.72
Drug-Gender Alert	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Inappropriate Billing	\$0.00	\$470.04	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$470.04
Missing Drug Therapy	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Dosage Form	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Dose	\$0.00	\$2,313.84	\$0.00	\$0.00	\$0.00	\$285.60	\$0.00	\$0.00	\$2,599.44
Not Optimal Drug	\$0.00	\$1,888.80	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1,888.80
Not Optimal Duration	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Patient Overuse	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Potential Generic Use	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Therapeutic Alternative	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$6,504.48	\$6,504.48
Therapeutic Duplication	\$12,238.68	\$26,957.40	\$5,043.48	\$7,130.88	\$19,262.40	\$10,331.40	\$8,378.52	\$2,722.92	\$92,065.68
Unnecessary Drug Therapy	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Total	\$12,238.68	\$31,630.08	\$5,043.48	\$7,130.88	\$19,262.40	\$10,617.00	\$8,427.24	\$9,227.40	\$103,577.16

Intervention Case Summaries

September 2009

The Commission reviewed the profile of a 55 year-old female taking *Invega* and clozapine concurrently. The Commission asked if the patient was refractory to clozapine alone and if there had been a measurable therapeutic benefit achieved with two antipsychotics. Upon re-review, *Invega* was discontinued. Annualized pre-rebate savings (state and federal) = \$ 4,471.54

The Commission reviewed the profile of a 60 year old female taking lithium in combination with HCTZ. The Commission asked if the prescriber was aware of the drug interaction between the two medications. Upon re-review, HCTZ was discontinued. Annualized pre-rebate savings (state and federal) = \$ 60.75

The Commission reviewed the profile of a 60 year-old female taking two atypical antipsychotics (Abilify and Seroquel) in combination with a typical antipsychotic (fluphenazine). The Commission asked if there has been a measurable therapeutic benefit achieved with the combination. Upon re-review, Abilify was discontinued. Annualized pre-rebate savings (state and federal) = \$ 12,258.67

The Commission reviewed the profile of a 30 year old female taking diazepam and lorazepam concurrently. The Commission asked if one of the medications could be discontinued with a dosage adjustment of the other, if needed, to control the members clinical situation. Upon re-review, the diazepam was discontinued. Annualized pre-rebate savings (state and federal) = \$80.69

Study 005
Initial – Nov 08
Re-review – Aug 09

Intervention Case Summaries

November 2009

The Commission reviewed the profile of a 55 year-old female taking oxybutynin er and oxybutynin ir concurrently. The Commission asked what the clinical situation was for the combined use of both the long acting and short acting form of oxybutynin and if one of the medications could be discontinued. Upon re-review, oxybutynin er was discontinued.

Annualized pre-rebate savings (state and federal) = \$1,049.87

The Commission reviewed the profile of a 48 year-old male taking methocarbamol and tizanidine concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, tizanidine was discontinued.

Annualized pre-rebate savings (state and federal) = \$188.60

The Commission reviewed the profile of a 49 year-old male taking alprazolam and temazepam concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, alprazolam was discontinued.

Annualized pre-rebate savings (state and federal) = \$143.26

The Commission reviewed the profile of a 53 year-old female taking *Zyprexa Zydis*. The Commission asked if swallowing oral medications is not a problem, if the member could use *Zyprexa* tablets. Upon re-review, the member was switched to *Zyprexa* tablets.

Annualized pre-rebate savings (state and federal) = \$776.16

Study 006

Initial – Dec 08

Re-review – Sep 09

Intervention Case Summaries

December 2009

The Commission reviewed the profile of a 57 year-old male taking doxazosin and terazosin concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, doxazosin was discontinued.

Annualized pre-rebate savings (state and federal) = \$110.68

The Commission reviewed the profile of a 56 year-old female taking gabapentin and *Lyrica* concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, gabapentin was discontinued.

Annualized pre-rebate savings (state and federal) = \$411.38

The Commission reviewed the profile of a 64 year-old female taking *Diovan* and enalapril concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, both medications were discontinued and metoprolol was started.

Annualized pre-rebate savings (state and federal) = \$1,001.10 (combined)

Annualized pre-rebate cost of metoprolol = \$50.06

Annualized pre-rebate net savings (state and federal) = \$951.04

The Commission reviewed the profile of a 46 year-old female taking *Ultram ER* in combination with *Cymbalta* and fluoxetine putting the member at an increased risk of serotonin syndrome. The Commission asked if the *Ultram ER* could be discontinued or changed to a less expensive pain mediation. Upon re-review, *Ultram ER*, *Cymbalta*, and fluoxetine were discontinued. Therapy was switched to *Lyrica* and *Savella*.

Annualized pre-rebate savings for *Ultram ER*, *Cymbalta*, and fluoxetine (state and federal) = \$8,570.42

Annualized pre-rebate cost for *Lyrica* and *Savella* (state and federal) = \$3,971.91

Annualized pre-rebate net savings (state and federal) = \$4,598.51

Study 009

Initial – Feb 09

Re-review – Nov 09

Intervention Case Summaries

March 2010

The Commission reviewed the profile of a 22 year-old male using Proair HFA and albuterol solution concurrently. The Commission asked what the clinical situation was for the combined use of these medications and if one or more of the medication(s) could be discontinued. Upon re-review, albuterol solution was discontinued.
Annualized pre-rebate savings (state and federal) = \$246.48

The Commission reviewed the profile of a 57 year-old male using *Combivent*, *Maxair* and Proair HFA concurrently. The Commission asked what the clinical situation was for the duplication of beta-2 adrenergic agonists in the medications and if one or more of the medication(s) could be discontinued. Upon re-review, Proair HFA was discontinued.
Annualized pre-rebate savings (state and federal) = \$969.66

The Commission reviewed the profile of a 54 year-old male taking tizanidine and methocarbamol concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, tizanidine was discontinued.
Annualized pre-rebate savings (state and federal) = \$76.51

The Commission reviewed the profile of a 25 year-old female taking alprazolam and diazepam concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, diazepam was discontinued.
Annualized pre-rebate savings (state and federal) = \$61.04

Intervention Case Summaries

May 2010

The Commission reviewed the profile of a 47 year-old female using alprazolam 8mg daily. The Commission asked if the dose was appropriate since the recommended adult dose for anxiety is 4mg per day. Upon re-review, the dose of alprazolam was decreased to 4mg daily.

Annualized pre-rebate savings (state and federal) = \$63.72

The Commission reviewed the profile of a 55 year-old female using misoprostol without an NSAID. The Commission asked if the misoprostol could be discontinued since it is indicated for the prevention of NSAID induced gastric ulcers. Upon re-review, misoprostol was discontinued.

Annualized pre-rebate savings (state and federal) = \$550.80

The Commission reviewed the profile of a 48 year-old female receiving oxybutynin and *Enblex* from different providers. The Commission asked if the prescriber was aware of the duplication and if one medication could be discontinued. Upon re-review, both oxybutynin and *Enblex* were discontinued.

Annualized pre-rebate savings (state and federal) = \$1,718.15

The Commission reviewed the profile of a 25 year-old female taking clonidine and guanfacine concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, guanfacine was discontinued.

Annualized pre-rebate savings (state and federal) = \$109.92

Study 015

Initial – June 09

Re-review – March 10

Intervention Case Summaries

June 2010

The Commission reviewed the profile of a 45 year-old male filling Keppra 500mg for a quantity of 300 tablets per 30 days. The Commission asked if the member could consolidate the dose by using Keppra 1000mg tablets thus decreasing the patients' daily pill burden and providing a cost savings to the State. Upon re-review, the dose was consolidated to 1000mg and the patient switched to generic levetiracetam. Annualized pre-rebate savings (state and federal) = \$13,565.19

The Commission reviewed the profile of a 58 year-old female using *Tiazac* and amlodipine concurrently. The Commission asked if one of the medications could be discontinued. Upon re-review, *Tiazac* was discontinued. Annualized pre-rebate savings (state and federal) = \$600.09

The Commission reviewed the profile of a 57 year-old female using *Advair* and *Serevent* concurrently. The Commission asked what the clinical situation was for the combined use of the two medications and if one medication could be discontinued. Upon re-review, *Advair* was discontinued. Annualized pre-rebate savings (state and federal) = \$1,720.79

The Commission reviewed the profile of a 29 year-old male taking immediate release *Seroquel* 25mg daily and *Seroquel XR* 300mg daily. The Commission asked what the clinical situation was requiring the use of two different dosage forms for this patient and if one dosage form could be discontinued with a dose adjustment of the other. Upon re-review, immediate release *Seroquel* was discontinued and the dose of *Seroquel XR* was changed to 250mg daily. Annualized pre-rebate savings (state and federal) = \$446.58

Appendix E

Results Problem-Focused

Problem Focus: Studies
SFY 2010

Focus	Review Period	Evaluation Period	Patients Reviewed	Total Cost Savings*
Members on a TZD with a Diagnosis of Congestive Heart Failure	7/1/2008 - 12/31/2008	4/1/2009 - 9/30/2009	72	\$273,111.22
Duplicate SSRI Utilization - Focus Study	8/1/2008 - 10/31/2008	4/1/2009 - 6/30/2009	15	\$34,893.96
Long Acting Narcotic plus Methadone - Focus Study	8/1/2008 - 11/30/2008	3/1/2009 - 6/30/2009	16	\$6,245.10
Duplicate Inhaled Anticholinergics (Tiotropium plus Ipratropium)	9/1/2008 - 11/30/2008	5/1/2009 - 7/31/2009	35	\$242,517.32
ACE Inhibitor + ARB	4/1/2009 - 6/30/2009	11/1/2009 - 1/31/2010	47	\$21,657.00
Tamoxifen + SSRI	5/1/2009 - 7/31/2009	12/1/2009 - 2/28/2010	16	\$1,029.12
Chronic Transdermal Scopolamine Use	7/1/2009 - 9/30/2009	4/1/2010 - 6/30/2010	24	\$10,078.96
Drugs Causing Edema Focus Study	1/1/2009 - 6/30/2009	1/1/2010 - 6/30/2010	1,400	\$91,956.56
TOTAL			1,625	\$681,489.24

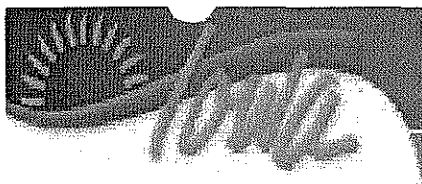
*Savings reported are pre-rebate, total dollars

Problem Focused Studies Impact Rate

Focus	Review Period	Evaluation Period	Patients Reviewed	Positive Impact	Impact Rate
Members on a TZD with a Diagnosis of Congestive Heart Failure	7/1/2008 - 12/31/2008	4/1/2009 - 9/30/2009	72	14	19.44%
Duplicate SSRI Utilization - Focus Study	8/1/2008 - 10/31/2008	4/1/2009 - 6/30/2009	15	10	66.67%
Long Acting Narcotic plus Methadone - Focus Study	9/1/2008 - 11/30/2008	3/1/2009 - 6/30/2009	16	6	37.50%
Duplicate Inhaled Anticholinergics (Tiotropium plus Ipratropium)	8/1/2008 - 11/30/2008	5/1/2009 - 7/31/2009	35	18	51.43%
ACE Inhibitor + ARB	4/1/2009 - 6/30/2009	11/1/2009 - 1/31/2010	47	26	55.32%
Tamoxifen + SSRI	5/1/2009 - 7/31/2009	12/1/2009 - 2/28/2010	16	6	37.50%
Chronic Transdermal Scopolamine Use	7/1/2009 - 9/30/2009	4/1/2010 - 6/30/2010	24	8	33.33%
Drugs Causing Edema Focus Study	1/1/2009 - 6/30/2009	1/1/2010 - 6/30/2010	1,400	479	34.21%
TOTAL			1,625	567	34.89%

Appendix F

Descriptions Problem-Focused



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service for a Three Month Time Frame (4/1/2009 to 6/30/2009)

Follow Up - Duplicate SSRI Therapy

Purpose: Follow-up on the 15 unique members identified as having duplicate SSRIs in their claims history for three consecutive months during the time frame 8/1/08 to 10/31/08. Letters were sent to providers at the end of December, 2008.

Number of unique members from original study 15

Number of unique members still using duplicate SSRI therapy after DUR intervention 5

Number of members who lost Medicaid eligibility since 9/1/2008 0

Number of surveys sent to prescribers	17	Number of surveys received from prescribers	3	Percent of surveys from prescribers	27.27%
Number of surveys sent to pharmacies	17	Number of surveys received from pharmacies	8	Percent of surveys from pharmacies	72.73%
Total Number of surveys sent	34	Total Number of surveys received	11	Percent of surveys received	32.35%

Costs (pre-rebate)	Original Costs (8/1/2008 - 10/31/2008)	Costs After DUR Intervention (4/1/2009 - 6/30/2009)	Cost Savings
Total Dollars (State and Federal)	\$20,729.09	\$12,005.60	\$8,723.49
Total Dollars Federal	\$13,898.85	\$8,049.75	\$5,849.10
Total Dollars State	\$6,830.24	\$3,955.85	\$2,874.39



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service between 8/1/2008 - 11/30/2008

Follow Up - Methadone in Combination with Long Acting Narcotics

Purpose: Follow-up on the 16 unique members identified as using methadone in combination with other long acting narcotics in their claims history during the time frame 8/1/08 to 11/30/08. Letters were sent to providers at the end of November, 2008.

Number of unique members from original study

16

Number of unique members still using methadone in combination with long acting narcotics after DUR intervention

10

Number of members who lost Medicaid eligibility since 3/1/2009

0

Number of surveys sent to prescribers

17

Number of surveys received from prescribers

5

Percent of surveys from prescribers

33.33%

Number of surveys sent to pharmacies

19

Number of surveys received from pharmacies

10

Percent of surveys from pharmacies

66.67%

Total number of surveys sent

36

Total number of surveys received

15

Percent of surveys received

41.67%

Costs (pre-rebate)	Original Costs (8/1/2008 - 11/30/2008)	Costs After DUR Intervention (3/1/2009 - 6/30/2009)	Cost Savings
Total Dollars (State and Federal)	\$32,594.96	\$30,513.26	\$2,081.70
Total Dollars Federal	\$21,854.92	\$20,459.14	\$1,395.78
Total Dollars State	\$10,740.04	\$10,054.12	\$685.92



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service for a Three Month Time Frame (5/1/2009 to 7/31/2009)

Follow Up - Duplicate Inhaled Anticholinergics

Purpose: Follow-up on the 35 unique members identified as having duplicate inhaled anticholinergics (tiotropium and ipratropium) in their claims history between the time period of 9/1/2008 through 11/30/2008. Letters were sent to providers in March, 2009.

Number of unique members from original study 35

Number of unique members still using duplicate inhaled anticholinergic therapy after DUR intervention 17

Number of members who lost Medicaid eligibility since 9/1/2008 0

Number of surveys sent to prescribers	40	Number of surveys received from prescribers	29	Percent of surveys from prescribers	65.91%
Number of surveys sent to pharmacies	84	Number of surveys received from pharmacies	15	Percent of surveys from pharmacies	34.09%
Total Number of surveys sent	124	Total Number of surveys received	44	Percent of surveys received	35.48%

Costs (pre-rebate)	Original Costs (9/1/2008 - 11/30/2008)	Costs After DUR Intervention (5/1/2009 - 7/31/2009)	Cost Savings
Total Dollars (State and Federal)	\$344,248.68	\$283,619.35	\$60,629.33
Total Dollars Federal	\$230,818.74	\$194,497.42	\$36,321.32
Total Dollars State	\$113,429.94	\$89,121.93	\$24,308.01



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service 7/1/2008 to 12/31/2008

**Follow Up - Members with a Diagnosis of
 Congestive Heart Failure that are also Taking a Thiazolidinedione (TZD)**

Purpose: Follow-up on the 72 unique members identified as having a diagnosis of CHF while on a TZD during the time frame 7/1/2008 through 12/31/2008. Letters were sent to providers in March 2009.

Number of unique members from original study	72				
Number of unique members that discontinued the TZD after DUR intervention	14				
Number of members who lost Medicaid eligibility since 9/1/2008	0				
Number of surveys sent to prescribers	75	Number of surveys received from prescribers	25	Percent of surveys from prescribers	48.08%
Number of surveys sent to pharmacies	77	Number of surveys received from pharmacies	27	Percent of surveys from pharmacies	51.92%
Total Number of surveys sent	152	Total Number of surveys received	52	Percent of surveys received	34.21%

Costs (pre-rebate)	Original Costs (7/1/2008 -12/31/2008)	Costs After DUR Intervention (4/1/2009 - 9/30/2009)	Cost Savings
Total Dollars (State and Federal)	\$453,022.98	\$316,467.37	\$136,555.61
Total Dollars Federal	\$303,751.91	\$218,287.30	\$94,489.65
Total Dollars State	\$149,271.07	\$98,180.07	\$42,065.96



Medicaid Enterprise

IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service 04/01/2009 to 06/30/2009

Purpose: Follow-up on the 47 unique members identified as using an Angiotensin Converting Enzyme (ACE) Inhibitor in combination with a Angiotensin Receptor Blocker (ARB), without a diagnosis of congestive heart failure, in their claims history during the time frame 4/1/09 to 6/30/09. Letters were sent to providers in October, 2009.

Number of unique members from original study 47

Number of unique members that discontinued use 26

Number of members who lost Medicaid eligibility since 7/1/2009 0

Number of surveys sent to prescribers	46	Number of surveys received from prescribers	24	Percent of surveys from prescribers	66.67%
Number of surveys sent to pharmacies	50	Number of surveys received from pharmacies	12	Percent of surveys from pharmacies	33.33%
Total Number of surveys sent	96	Total Number of surveys received	36	Percent of surveys received	37.50%

Costs (pre-rebate)	Original Costs (04/01/2009 -06/30/2009)	Costs After DUR Intervention (11/01/2009 - 01/31/2010)	Cost Savings
Total Dollars (State and Federal)	\$14,563.56	\$9,149.31	\$5,414.25
Total Dollars Federal	\$10,022.64	\$6,637.82	\$3,928.04
Total Dollars State	\$4,540.92	\$2,511.49	\$1,486.21



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service between 5/1/2009 - 7/31/2009

Follow Up - Tamoxifen in Combination with SSRI

Purpose: Follow-up on the 16 unique members identified as using tamoxifen in combination with an SSRI that is a strong or mild inhibitor of CYP2D6, in their claims history during the time frame 5/1/09 to 7/31/09. Letters were sent to providers in October, 2009.

Number of unique members from original study	16	Number of members who lost Medicaid eligibility since	0		
Number of unique members that discontinued use of the SSRI	0	Number of unique members that did not change therapy	5		
Number of unique members that discontinued use of tamoxifen of which 3 member(s) were taking an Aromatase Inhibitor during the original time period and continued therapy through the follow-up period	5	Number of unique members that discontinued use of both SSRI and tamoxifen of which 1 member(s) were taking an Aromatase Inhibitor during the original time period and continued therapy through the follow-up period	6		
Number of surveys sent to prescribers	20	Number of surveys received from prescribers	8	Percent of surveys from prescribers	40.00%
Number of surveys sent to pharmacies	20	Number of surveys received from pharmacies	9	Percent of surveys from pharmacies	45.00%
Total number of surveys sent	40	Total number of surveys received	17	Percent of surveys received	42.50%

Costs (pre-rebate)	Original Costs (5/1/2009 - 7/31/2009)	Costs After DUR Intervention (12/1/2009 - 2/28/2010)	Cost Savings	Annualized Cost Savings ***
Total Dollars Federal	\$416.37	\$248.30	\$186.66	\$734.48
Total Dollars State	\$183.15	\$93.94	\$70.62	\$294.64
Total Dollars (State and Federal)	\$599.52	\$342.24	\$257.28	\$1,029.12

*** Annualized Cost Savings is based on the reported interval.



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service between 7/1/09 - 9/30/09

Follow-Up - Transdermal Scopolamine on a Chronic Basis

Purpose: Follow-up on the 24 unique members identified as using transdermal scopolamine on a chronic basis during the time frame 7/1/09 to 9/30/09. Letters were sent to providers in December, 2009.

Number of unique members from original study	24				
Number of unique members that changed therapy	8				
Number of unique members that did not change therapy	14				
Number of members who lost Medicaid eligibility since 10/1/2009	2				
Number of surveys sent to prescribers	34	Number of surveys received from prescribers	26	Percent of surveys from prescribers	76.47%
Number of surveys sent to pharmacies	34	Number of surveys received from pharmacies	22	Percent of surveys from pharmacies	64.71%
Total number of surveys sent	68	Total number of surveys received	48	Percent of surveys received	70.59%

Costs (pre-rebate)	Original Costs (7/1/09 - 9/30/09)	Costs After DUR Intervention (4/1/10 - 6/30/10)	Additional Drug Costs (4/1/10 - 6/30/10)	Cost Savings	Annualized Cost Savings ***
Total Dollars Federal	\$4,408.53	\$2,996.08	\$300.91	\$1,713.35	\$6,853.41
Total Dollars State	\$1,826.13	\$1,133.60	\$113.85	\$806.39	\$3,225.55
Total Dollars (State and Federal)	\$6,234.66	\$4,129.68	\$414.76	\$2,519.74	\$10,078.96

*** Annualized Cost Savings is based on the reported interval.



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-reversed Claims
Dates of Service between 01/01/2009 - 06/30/2009

Follow-Up - Medication that Typically Causes Edema as a Side Effect

Purpose: Follow-up on the unique members identified as using a medication that typically causes edema as a side effect in a disease state that often has edema present as a symptom during the time frame 01/01/2009 to 06/30/2009. Letters were sent to providers in December, 2009.

Number of unique members from original study 1,400

Number of unique members that changed therapy 479

Number of unique members that did not change therapy 741

Number of members who lost Medicaid eligibility since 07/01/2009 180

Number of surveys sent to prescribers	1,012	Number of surveys received from prescribers	528	Percent of surveys from prescribers	52.17%
Number of surveys sent to pharmacies	495	Number of surveys received from pharmacies	244	Percent of surveys from pharmacies	49.29%
Total number of surveys sent	1,507	Total number of surveys received	772	Percent of surveys received	51.23%

Costs (pre-rebate)	Original Costs (01/01/2009 - 06/30/2009)	Costs After DUR Intervention (01/01/2010 - 06/30/2010)	Cost Savings	Annualized Cost Savings ***
Total Dollars Federal	\$188,997.71	\$165,884.02	\$33,357.24	\$65,629.40
Total Dollars State	\$85,628.43	\$62,763.84	\$12,621.04	\$26,327.16
Total Dollars (State and Federal)	\$274,626.14	\$228,647.86	\$45,978.28	\$91,956.56

*** Annualized Cost Savings is based on the reported interval.

Appendix G

Prior Auth Recommendations

2009-2010 Therapeutic Prior Authorization Criteria Review

During the fiscal year ending 2010, the Commission reviewed the following categories of medications covered under the prior authorization program.

The following criteria were reviewed with recommended changes:

- Antihistamines – Modifications were made to require three unsuccessful trials with antihistamines that do not require PA, two of which must be loratadine and cetirizine for patients 21 years and older prior to approval of non-preferred first generation or preferred second generation prescription antihistamine. For patients 20 years of age and younger members must have trials with cetirizine and loratadine prior to approval of non-preferred first generation or preferred second generation prescription antihistamine.
- Ketorolac – Modifications were made to require trials of two preferred NSAIDs prior to consideration of IV/IM ketorolac.
- Muscle Relaxants – Modifications were made to add a quantity limit to carisoprodol of 120 tablets per 180 days at a maximum dose of 4 tablets per day when the criteria for coverage is met.
- Biologicals for Ankylosing Spondylitis – Modifications were made to require inadequate responses to two preferred NSAIDs at maximum therapeutic doses. Trials should be at least 3 months in duration. Requests for patients with symptoms of peripheral arthritis must also have failed a 30-day trial with at least one conventional DMARD.
- Biologicals for Arthritis – Modifications were made to remove preferred DMARD trials (with d-penicillamine, azathioprine, oral gold and/or intramuscular gold) and to add minocycline as a preferred oral DMARD trial.
- Proton Pump Inhibitors (PPI) – Modifications were made to decrease the age for use of Prevacid SoluTabs to 8 years old or younger. Language was also added to address twice daily dosing, requiring a retrial of the recommended once daily dosing after a 3 month period at twice daily dosing.
- Smoking Cessation Therapy – Modifications were made to the Varenicline PA criteria by adding bupropion SR that is FDA approved for smoking cessation and changed the name of the PA.

The following are new classes for which clinical prior authorization criteria were developed and recommended:

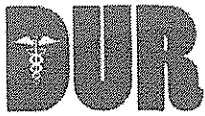
- Febuxostat (*Uloric*) – Prior authorization criteria was developed and accepted to require a trial of allopurinol 300mg per day when symptoms of gout still persist although being treated with allopurinol.
- Thrombopoietin Receptor Agonists – Prior authorization criteria was developed and accepted to require a diagnosis for chronic immune thrombocytopenic purpura (ITP), including documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the member has undergone a splenectomy.
- Dipeptidyl Peptidase-4 (DPP-4) Inhibitors – Prior authorization criteria was developed and accepted to require a diagnosis of Type 2 Diabetes Mellitus, age

of 18 years or older, and unable to reach HbA1C goals using a combination of two or more antidiabetic medications at maximum tolerated doses.

- Short Acting Narcotics – Prior authorization criteria was developed and accepted to require trials and therapy failure with three chemically distinct preferred short acting narcotics at therapeutic doses.
- Lidocaine Patch – Prior authorization criteria was developed and accepted to require a diagnosis of post-herpetic neuralgia and treatment failure with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.
- Chronic Pain Syndromes – Prior authorization criteria was developed and accepted for duloxetine, pregabalin, and milnacipran to require: 1) a diagnosis of fibromyalgia and a trial and therapy failure at a therapeutic dose with three drugs from three distinct therapeutic classes (tricyclic antidepressant, muscle relaxant, SSRI/SNRI, or gabapentin) with documented non-pharmacologic therapies and documentation of previous trial and therapy failure at a therapeutic dose with milnacipran when duloxetine or pregabalin are requested. 2) A diagnosis of post-herpetic neuralgia with a trial and therapy failure at a therapeutic dose with at least two drugs from two distinct therapeutic classes (tricyclic antidepressant, topical lidocaine, valproate, carbamazepine, or gabapentin). 3) A diagnosis of diabetic peripheral neuropathy with a trial and therapy failure at a therapeutic dose with at least two drugs from two distinct classes (tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin). 4) A diagnosis of partial onset seizures, as adjunct therapy. 5) A diagnosis of major depressive disorder or generalized anxiety disorder.

The following criteria were recommended to be removed:

- Ergotamine Derivatives – Prior authorization criteria was removed for this category due to low utilization of this category of drugs.



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

August 12, 2009

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 5, 2009. At this meeting, the DUR Commission members discussed the Thrombopoietin Receptor Agonists and Palivizumab (*Synagis*) clinical prior authorization criteria. The following recommendations have been made by the DUR Commission:

Since no comments were received from medical associations or the Iowa Pharmacy Association in response to a June 4th letter that was sent to them detailing the proposed Thrombopoietin Receptor Agonists criteria, the DUR Commission recommends the following criteria be considered for implementation:

Thrombopoietin Receptor Agonists:

Newly Proposed Criteria: Payment for a preferred thrombopoietin receptor agonist will only be considered for cases in which there is a diagnosis of chronic immune thrombocytopenic purpura (ITP) in addition to documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the member has undergone a splenectomy. Payment for a non-preferred thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred thrombopoietin receptor agonist unless such a trial would be medically contraindicated.

The DUR Commission also reviewed the new *Red Book* guidelines on RSV prevention to determine if changes needed to be made to the Palivizumab (*Synagis*) Clinical PA criteria. Since the evidence supporting the new *Red Book* guidelines have not yet been made available, the Commission recommended making no changes to the PA criteria for the 2009-10 RSV season. They went on to recommend that approved prior authorizations be given a November 1st (2009) start date for 5 doses initially. Requests for additional doses after the initial five towards the end of the season will be

reviewed on a case-by-case basis based on Centers for Disease Control & Prevention (CDC) and Iowa Department of Public Health virology data specific to Iowa and the Midwest.

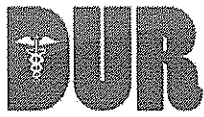
Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for clinical prior authorization criteria for Thrombopoietin Receptor Agonists, and adopting the recommendations for coverage of *Synagis* for the 2009-10 RSV season.

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph.". The signature is written in a cursive style with a large, looped initial "P".

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

September 3, 2009

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, September 2, 2009. At this meeting, the DUR Commission members discussed the febuxostat (*Uloric*) and Palivizumab (*Synagis*) clinical prior authorization criteria. The following recommendations have been made by the DUR Commission:

Following a review of the comments submitted by members of the Iowa Pharmacy Association (no comments were received from medical associations) in response to an August 6th letter that was sent to them detailing the proposed febuxostat (*Uloric*) criteria, the DUR Commission recommends the following criteria be considered for implementation:

Febuxostat (*Uloric*):

Newly Proposed Criteria: Prior authorization is required for febuxostat (*Uloric*). Payment for febuxostat (*Uloric*) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

The Commission members felt as though it were more important to manage a member's symptoms of gout, as opposed to "chasing" uric acid levels, and therefore, did not recommend monitoring of uric acid levels to be a part of the criteria. Additionally, the Commission recommended a quantity limit of 30 tablets per 30 days be placed on the *Uloric* 40mg tablets.

The DUR Commission also reviewed the American Academy of Pediatrics Position Statement on the new *Red Book Guidelines* for RSV prevention to determine if changes needed to be made to the Palivizumab (*Synagis*) Clinical PA criteria. It was felt that the evidence supporting the new *Red Book* guidelines contained no new clinical data, only new pharmacoeconomic modeling data. Therefore, the Commission again recommended making no changes to the PA criteria for the 2009-10 RSV season.

They went on to revise their original recommendation in that approved prior authorizations be given a November 16th (2009) start date for a maximum of 5 doses. It was felt that by pushing back the start date, more children would be covered for *Synagis* during the peak of the RSV season in Iowa.

The Commission also voted in favor of giving the Department authority to replace the words "adequate dose(s)" with "therapeutic dose(s)", throughout the clinical PA Criteria without having to review each individual category.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for clinical prior authorization criteria and quantity limit for Febuxostat (*Uloric*), and adopting the recommendations for coverage of *Synagis* for the 2009-10 RSV season.

Sincerely,

A handwritten signature in cursive script that reads "Paula Smith R.Ph.".

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

November 5, 2009

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 4, 2009. At this meeting, the DUR Commission members discussed the Ketorolac, Muscle Relaxants, Antihistamines, and Fentanyl Short Acting Oral Products clinical prior authorization criteria. The following recommendations have been made by the DUR Commission:

Since no comments were received from medical associations or the Iowa Pharmacy Association in response to a September 8th letter that was sent to them detailing the proposed Ketorolac, Muscle Relaxants, Antihistamines, and Fentanyl Short Acting Oral Products criteria, the DUR Commission recommends the following criteria be considered for implementation:

Ketorolac:

Newly Proposed Criteria:

Prior authorization is required for ketorolac tromethamine, a nonsteroidal anti-inflammatory drug indicated for short term (up to five days) management of moderately severe, acute pain. It is NOT indicated for minor or chronic conditions.

This product carries a **Black Box Warning**. Initiate therapy with IV/IM and use oral ketorolac tromethamine only as a continuation therapy to ketorolac tromethamine IV/IM. The combined duration of use of IV/IM and oral is not to exceed five (5) days. Payment will be approved under the following conditions:

1. For oral therapy, documentation of recent IM/IV ketorolac tromethamine injection including administration date and time, and the total number of injections given.
2. Request falls within the manufacturer's dosing guidelines. Maximum oral dose is 40mg/day. Maximum IV/IM dose is 120mg/day. Maximum duration of therapy is 5 days per month.
3. Diagnosis indicating moderately severe, acute pain.

Requests for IV/IM ketorolac must document previous trials and therapy failures with at least two preferred nonsteroidal anti-inflammatory drugs at adequate doses.

Muscle Relaxants

Newly proposed criteria:

Prior authorization is required for non-preferred muscle relaxants. Payment for non-preferred muscle relaxants will be authorized only for cases in which there is documentation of previous trials and therapy failures with at least three preferred muscle relaxants. *Requests for carisoprodol will be approved for a maximum of 120 tablets per 180 days at a maximum dose of 4 tablets per day when the criteria for coverage are met.*

Antihistamines

Newly proposed criteria:

Prior authorization is required for all non-preferred antihistamines and preferred second generation prescription antihistamines.

Patients 21 years of age and older must have *three* unsuccessful trials with antihistamines that do not require prior authorization, prior to the approval of a non-preferred first generation or preferred second generation prescription antihistamine. *Two* of the trials must be *with* cetirizine *and* loratadine. Prior to approval of a non-preferred second generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred second generation prescription antihistamine.

Patients 20 years of age and younger must have unsuccessful trials *with* cetirizine *and* loratadine prior to the approval of a non-preferred first generation or preferred second generation prescription antihistamine. Prior to approval of a non-preferred second generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred second generation prescription antihistamine.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Fentanyl, Short Acting Oral Products

Newly proposed criteria:

Prior authorization is required for short acting oral fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients. These products carry a **Black Box Warning**.

Actiq®, Fentora®, and *Onsolis*™:

- Are indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain.
- Are contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, do not use in opioid non-tolerant patients.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for clinical prior authorization criteria for Ketorolac, Muscle Relaxants, Antihistamines, and Fentanyl Short Acting Oral Products.

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive style with a large initial 'P'.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

December 2, 2009

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, December 2, 2009. At this meeting, the DUR Commission members discussed the Smoking Cessation Therapy, Proton Pump Inhibitors, Biologicals for Ankylosing Spondylitis, and Short Acting Narcotics clinical prior authorization criteria. The following recommendations have been made by the DUR Commission:

Since no comments were received from medical associations or the Iowa Pharmacy Association in response to a November 6th letter that was sent to them detailing the proposed Smoking Cessation Therapy, Proton Pump Inhibitors, Biologicals for Ankylosing Spondylitis, and Short Acting Narcotics criteria, the DUR Commission recommends the following criteria be considered for implementation:

Smoking Cessation Therapy (Replaces Current Varenicline PA Criteria)

Newly Proposed Criteria:

Prior Authorization is required for varenicline (Chantix™) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.*
- 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.*
- 3) Approvals will only be granted for patients eighteen years of age and older.*
- 4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.*
- 5) Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.*

6) *The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation*

Proton Pump Inhibitors

Changes are italicized:

Prior authorization is not required for the preferred proton pump inhibitors (PPI) for a cumulative 60-days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization. Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of:

1. Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2. Barrett's esophagus.
3. Erosive esophagitis
4. Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses.
5. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of *Helicobacter pylori* treatment or a negative *Helicobacter pylori* test result.

Prior authorization is NOT required for Prevacid SoluTabs for children age 8 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid SoluTabs for patients over 8 years of age beginning day one of therapy. Authorization for Prevacid SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Biologicals for Ankylosing Spondylitis

Changes are italicized:

Prior authorization is required for biologicals used for ankylosing spondylitis.

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold and/or intramuscular gold.

Prior authorization is required for all non-preferred biologicals for ankylosing spondylitis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

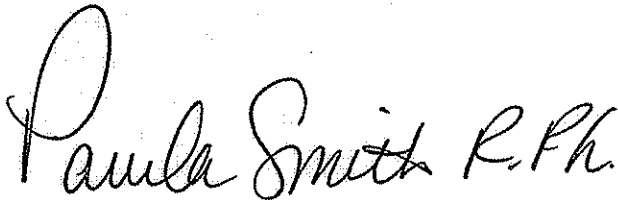
Short Acting Narcotics

Newly proposed criteria:

Prior authorization is required for all non-preferred short acting narcotics. Payment will be considered for cases in which there is documentation of previous trial(s) and therapy failures with three (3) chemically distinct preferred short acting narcotics (based on narcotic ingredient only) at therapeutic doses, unless evidence is provided that the use of these products would be medically contraindicated.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for clinical prior authorization criteria for Smoking Cessation Therapy, Proton Pump Inhibitors, Biologicals for Ankylosing Spondylitis, and Short Acting Narcotics.

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive, flowing style.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 974-3131 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

February 4, 2010

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 3, 2010. At this meeting, the DUR Commission members discussed the proposed age limit on armodafinil (Nuvigil®), as well as changes to the Biologicals for Arthritis prior authorization criteria, and the addition of new prior authorization criteria for DPP-4 Inhibitors and Lidocaine Patch, and the removal of the Ergotamine Derivatives prior authorization criteria. The following recommendations have been made by the DUR Commission:

Since no comments were received from medical associations or the Iowa Pharmacy Association in response to a December 4th letter that was sent to them detailing these proposed changes, the DUR Commission recommends the following criteria be considered for implementation:

Pro-DUR Edit

Armodafinil (Nuvigil®)

An age edit to restrict use to members 17 years of age and older.

Prior Authorization Criteria

Biologicals for Arthritis

Modified PA Criteria:

Prior authorization is required for biologicals used for arthritis.

Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, *or* minocycline.

Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

DPP-4 Inhibitors

Newly proposed criteria:

Prior Authorization is required for dipeptidyl peptidase-4 (DPP-4) inhibitors. Payment will be considered under the following conditions:

- 1) A diagnosis of Type 2 diabetes mellitus,*
- 2) Patient is 18 years of age or older,*
- 3) The patient has not achieved HbA1C goals using a combination of two or more antidiabetic medications (metformin, sulfonylurea, thiazolidinedione, or insulin) at maximum tolerated doses unless otherwise contraindicated.*

Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in HbA1C since the beginning of the initial prior authorization period.

Lidocaine Patch (Lidoderm®)

Newly proposed criteria:

Prior authorization is required for topical lidocaine patches (Lidoderm). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

A quantity limit of 90 patches per 30 days will be added.

Ergotamine Derivatives

Existing criteria to be removed:

Prior authorization is required for preferred ergotamine derivatives used for migraine headache treatment for quantities exceeding 18 unit doses of tablets, injections, or sprays per 30 days.

Payment for ergotamine derivatives for migraine headache treatment beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred ergotamine derivatives beginning the first day of therapy. Payment for non-preferred Ergotamine agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. For consideration, the following information must be supplied:

- 1. The diagnosis requiring therapy.*
- 2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.*

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for the Pro-DUR edit on armodafinil (Nuvigil®), and the clinical prior authorization criteria for Biologicals for Arthritis, DPP-4 Inhibitors, Lidocaine Patch, and Ergotamine Derivatives.

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive style with a large initial 'P'.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 974-3131 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.

DUR Project Coordinator

Chad Bissell, Pharm.D.

March 4, 2010

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, March 3, 2010. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™). The following recommendations have been made by the DUR Commission:

Since no comments were received from the medical associations or the Iowa Pharmacy Association in response to a February 4th letter that was sent to them detailing the proposed duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™) criteria, the DUR Commission recommends the following criteria be considered for implementation:

Prior Authorization Criteria

Duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™)
(Replaces the current Pregabalin (Lyrica®) PA)

Newly Proposed PA Criteria:

Prior Authorization is required for *duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™)*. Payment will be considered under the following conditions:

1. A diagnosis of fibromyalgia (*Cymbalta®, Lyrica®, and Savella™*)
 - a. *a trial and therapy failure at a therapeutic dose with three drugs from any of the following: tricyclic antidepressant, muscle relaxant, second generation antidepressant, tramadol, or gabapentin, WITH*
 - b. *documented non-pharmacologic therapies (cognitive behavior therapies, exercise etc.), AND*
 - c. *documentation of a previous trial and therapy failure at a therapeutic dose with Savella™, when Cymbalta® and Lyrica® are requested.*

2. A diagnosis of post-herpetic neuralgia (*Lyrice*[®])
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, *valproate*, *carbamazepine*, or gabapentin.
3. A diagnosis of diabetic peripheral neuropathy (*Cymbalta*[®] and *Lyrice*[®])
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin.
4. A diagnosis of partial onset seizures, as adjunct therapy (*Lyrice*[®])
5. A diagnosis of major depressive disorder or generalized anxiety disorder (*Cymbalta*[®])

The DUR Commission discussed the format of the draft PA form presented at the meeting, combining the three medications. The DUR Commission would like the opportunity to further discuss development of the PA form(s) for these criterion prior to it becoming effective.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for the prior authorization criteria for duloxetine (*Cymbalta*[®]), pregabalin (*Lyrice*[®]), and milnacipran (*Savella*[™]).

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive, flowing style.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME

Appendix H

Prospective DUR

The following prospective DUR edits were recommended to the Department by the Commission in State FYE 2010.

- Quantity Limit of 30 tablets per 30 days on *Uloric* 40mg tablets.
- Point of Sale age edit on *Nuvigil* to restrict use to members 17 years of age and older.
- Quantity Limit of 120 tablets per 180 days at a maximum dose of four tablets per day for carisoprodol when the criteria for coverage is met.



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

September 3, 2009

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, September 2, 2009. At this meeting, the DUR Commission members discussed the febuxostat (*Uloric*) and Palivizumab (*Synagis*) clinical prior authorization criteria. The following recommendations have been made by the DUR Commission:

Following a review of the comments submitted by members of the Iowa Pharmacy Association (no comments were received from medical associations) in response to an August 6th letter that was sent to them detailing the proposed febuxostat (*Uloric*) criteria, the DUR Commission recommends the following criteria be considered for implementation:

Febuxostat (*Uloric*):

Newly Proposed Criteria: Prior authorization is required for febuxostat (*Uloric*). Payment for febuxostat (*Uloric*) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

The Commission members felt as though it were more important to manage a member's symptoms of gout, as opposed to "chasing" uric acid levels, and therefore, did not recommend monitoring of uric acid levels to be a part of the criteria. Additionally, the Commission recommended a quantity limit of 30 tablets per 30 days be placed on the *Uloric* 40mg tablets.


The DUR Commission also reviewed the American Academy of Pediatrics Position Statement on the new *Red Book Guidelines* for RSV prevention to determine if changes needed to be made to the Palivizumab (*Synagis*) Clinical PA criteria. It was felt that the evidence supporting the new *Red Book* guidelines contained no new clinical data, only new pharmacoeconomic modeling data. Therefore, the Commission again recommended making no changes to the PA criteria for the 2009-10 RSV season.

They went on to revise their original recommendation in that approved prior authorizations be given a November 16th (2009) start date for a maximum of 5 doses. It was felt that by pushing back the start date, more children would be covered for *Synagis* during the peak of the RSV season in Iowa.

The Commission also voted in favor of giving the Department authority to replace the words "adequate dose(s)" with "therapeutic dose(s)", throughout the clinical PA Criteria without having to review each individual category.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for clinical prior authorization criteria and quantity limit for Febuxostat (*Uloric*), and adopting the recommendations for coverage of *Synagis* for the 2009-10 RSV season.

Sincerely,

A handwritten signature in cursive script that reads "Paula Smith R.Ph.".

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 974-3131 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.

DUR Project Coordinator

Chad Bissell, Pharm.D.

February 4, 2010

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 3, 2010. At this meeting, the DUR Commission members discussed the proposed age limit on armodafinil (Nuvigil®), as well as changes to the Biologicals for Arthritis prior authorization criteria, and the addition of new prior authorization criteria for DPP-4 Inhibitors and Lidocaine Patch, and the removal of the Ergotamine Derivatives prior authorization criteria. The following recommendations have been made by the DUR Commission:

Since no comments were received from medical associations or the Iowa Pharmacy Association in response to a December 4th letter that was sent to them detailing these proposed changes, the DUR Commission recommends the following criteria be considered for implementation:

Pro-DUR Edit

Armodafinil (Nuvigil®)

An age edit to restrict use to members 17 years of age and older.

Prior Authorization Criteria

Biologicals for Arthritis

Modified PA Criteria:

Prior authorization is required for biologicals used for arthritis.

Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline.

Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

DPP-4 Inhibitors

Newly proposed criteria:

Prior Authorization is required for dipeptidyl peptidase-4 (DPP-4) inhibitors. Payment will be considered under the following conditions:

- 1) A diagnosis of Type 2 diabetes mellitus,*
- 2) Patient is 18 years of age or older,*
- 3) The patient has not achieved HbA1C goals using a combination of two or more antidiabetic medications (metformin, sulfonylurea, thiazolidinedione, or insulin) at maximum tolerated doses unless otherwise contraindicated.*

Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in HbA1C since the beginning of the initial prior authorization period.

Lidocaine Patch (Lidoderm®)

Newly proposed criteria:

Prior authorization is required for topical lidocaine patches (Lidoderm). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

A quantity limit of 90 patches per 30 days will be added.

Ergotamine Derivatives

Existing criteria to be removed:

Prior authorization is required for preferred ergotamine derivatives used for migraine headache treatment for quantities exceeding 18 unit doses of tablets, injections, or sprays per 30 days. Payment for ergotamine derivatives for migraine headache treatment beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred ergotamine derivatives beginning the first day of therapy. Payment for non-preferred Ergotamine agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. For consideration, the following information must be supplied:

1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendation for the Pro-DUR edit on armodafinil (Nuvigil®), and the clinical prior authorization criteria for Biologicals for Arthritis, DPP-4 Inhibitors, Lidocaine Patch, and Ergotamine Derivatives.

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive, flowing style.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME

Appendix I

FUL



Center for Medicaid and State Operations

DATE: June 17, 2009

FROM: Director
Pharmacy Division

SUBJECT: Notification of Medicaid Drug Federal Upper Limit (FUL) Changes to
Transmittal No. 37, Dated November 20, 2001

TO: Associate Regional Administrators, Division of Medicaid and State Operations

Please inform the States in your region of the following FUL changes as soon as possible. The changes are to be implemented no later than July 17, 2009.

CMS used the following compendia sources in compiling this list:
B – Blue Book, M – Medi-Span, R – Red Book

FUL Deletions

Generic Name

Meclizine 25 mg, Tablet, Oral, 100

FUL Decreases

Generic Name

FUL Price

Atenolol

25 mg, Tablet, Oral, 100

\$ 0.0459 B

50 mg, Tablet, Oral, 100

\$ 0.0500 B

100 mg, Tablet, Oral, 100

\$ 0.0690 B

Cefadroxil/Cefadroxil Hemihydrate

500 mg, Capsule, Oral, 50

\$ 0.7830 B

Clindamycin Hydrochloride

EQ 150 mg Base, Capsule, Oral, 100

\$ 0.2153 R

EQ 300 mg Base, Capsule, Oral, 100

\$ 1.1975 R

Dicyclomine Hydrochloride

10 mg, Capsule, Oral, 100

\$ 0.0885 R

20 mg, Tablet, Oral, 100

\$ 0.0405 M

FUL Price Decreases – continued

<u>Generic Name</u>	<u>FUL Price</u>
Gabapentin	
600 mg, Tablet, Oral, 100	\$ 0.9738 B
800 mg, Tablet, Oral, 100	\$ 1.1756 B
Gemfibrozil	
600 mg, Tablet, Oral, 500	\$ 0.1350 B
Halobetasol Propionate	
0.05%, Cream, Topical, 50	\$ 0.4800 B
0.05%, Ointment, Topical, 50	\$ 0.5325 B
Hydroxychloroquine Sulfate	
200 mg, Tablet, Oral, 100	\$ 0.2250 B
Lisinopril; Hydrochlorothiazide	
10 mg; 12.5 mg, Tablet, Oral, 100	\$ 0.2097 R
20 mg; 12.5 mg, Tablet, Oral, 100	\$ 0.2199 R
20 mg; 25 mg, Tablet, Oral, 100	\$ 0.2225 R
Pravastatin Sodium	
10 mg, Tablet, Oral, 90	\$ 0.2500 B
20 mg, Tablet, Oral, 90	\$ 0.2917 B
40 mg, Tablet, Oral, 90	\$ 0.3560 B

FUL Increases

<u>Generic Name</u>	<u>FUL Price</u>
Propranolol Hydrochloride	
60 mg, Tablet, Oral, 100	\$ 1.2792 B

FUL Additions

<u>Generic Name</u>	<u>FUL Price</u>
Metformin Hydrochloride	
500 mg, Tablet, Extended Release, Oral, 100	\$ 0.1307 R
750 mg, Tablet, Extended Release, Oral, 100	\$ 0.3368 R
Topiramate	
25 mg, Tablet, Oral, 60	\$ 0.2420 R
50 mg, Tablet, Oral, 60	\$ 0.4815 R
100 mg, Tablet, Oral, 60	\$ 0.6593 R
200 mg, Tablet, Oral, 60	\$ 0.7718 R

These changes will be posted to our website at <http://www.cms.hhs.gov/Reimbursement>. If you have any questions, please contact Gail Sexton at gail.sexton@cms.hhs.gov, telephone number (410) 786-4583 or Meagan Khau at meagan.khau@cms.hhs.gov, telephone number (410) 786-1357.

/s/

Larry Reed
Director, Division of Pharmacy

cc: Regional Administrators



Center for Medicaid and State Operations

DATE: July 29, 2009

FROM: Director
Pharmacy Division

SUBJECT: Notification of Medicaid Drug Federal Upper Limit (FUL) Changes to
Transmittal No. 37, Dated November 20, 2001

TO: Associate Regional Administrators, Division of Medicaid and State Operations

Please inform the States in your region of the following FUL changes as soon as possible. The changes are to be implemented no later than August 28, 2009.

CMS used the following compendia sources in compiling this list:
B – Blue Book, M – Medi-Span, R – Red Book

FUL Deletions

Generic Name

Desipramine Hydrochloride
25 mg, Tablet, Oral, 100
50 mg, Tablet, Oral, 100
75 mg, Tablet, Oral, 100
100 mg, Tablet, Oral, 100
150 mg, Tablet, Oral, 100

FUL Additions

Generic Name

FUL Price

Clindamycin Phosphate EQ 1% Base, Gel, Topical, 60 gm	\$ 0.7647 B
Clobetasol Propionate 0.05%, Aerosol, Foam, Topical, 100 gm	\$ 2.9796 B
Desogestrel; Ethinyl Estradiol 0.15 mg; 0.03 mg, Tablet, Oral, 28	\$ 1.0950 B
Divalproex Sodium EQ 125 mg, Valproic Acid, Capsule, Delayed Release Pellets, Oral, 100	\$ 0.8210 M

FUL Additions - continued

<u>Generic Name</u>	<u>FUL Price</u>
Hydrocortisone Butyrate 0.1%, Solution, Topical, 20 ml	\$ 0.3788 B
Hydromorphone Hydrochloride 2 mg, Tablet, Oral, 100	\$ 0.2184 B
Lamotrigine 5 mg, Tablet, Chewable, Oral, 100	\$ 0.6609 B
25 mg, Tablet, Chewable, Oral, 100	\$ 0.6923 B
25 mg, Tablet, Oral, 100	\$ 0.3035 B
100 mg, Tablet, Oral, 100	\$ 0.3467 B
150 mg, Tablet, Oral, 60	\$ 0.3800 B
200 mg, Tablet, Oral, 60	\$ 0.4135 B
Metoprolol Succinate EQ 100 mg Tartrate, Tablet, Extended Release, Oral, 100	\$ 1.4238 R
EQ 200 mg Tartrate, Tablet, Extended Release, Oral, 100	\$ 2.2650 R
Metronidazole 0.75%, Lotion, Topical, 59 ml	\$ 1.1695 R
Mycophenolate Mofetil 250 mg, Capsule, Oral, 100	\$ 0.5291 R
500 mg, Tablet, Oral, 100	\$ 1.0580 R
Omeprazole 40 mg, Capsule, Delayed Release Pellets, Oral, 100	\$ 1.7343 R
Rifampin 150 mg, Capsule, Oral, 30	\$ 1.4780 R
Stavudine 15 mg, Capsule, Oral, 60	\$ 2.2555 B
20 mg, Capsule, Oral, 60	\$ 2.3457 B
30 mg, Capsule, Oral, 60	\$ 2.4912 B
40 mg, Capsule, Oral, 60	\$ 2.6875 B

These changes will be posted to our website at <http://www.cms.hhs.gov/Reimbursement>. If you have any questions, please contact Gail Sexton at gail.sexton@cms.hhs.gov, telephone number (410) 786-4583 or Meagan Khau at meagan.khau@cms.hhs.gov, telephone number (410) 786-1357.

/s/

Larry Reed
Director, Division of Pharmacy

cc: Regional Administrators



Center for Medicaid and State Operations

DATE: August 26, 2009

FROM: Director
Pharmacy Division

SUBJECT: Notification of Medicaid Drug Federal Upper Limit (FUL) Changes to
Transmittal No. 37, Dated November 20, 2001

TO: Associate Regional Administrators, Division of Medicaid and State Operations

Please inform the States in your region of the following FUL changes as soon as possible. The changes are to be implemented no later than September 25, 2009.

CMS used the following compendia sources in compiling this list:
B – Blue Book, M – Medi-Span, R – Red Book

FUL Deletions

Generic Name

Erythromycin

0.5%, Ointment, Ophthalmic, 3

Metoprolol Succinate

EQ 100 mg, Tartrate, Tablet, Extended Release, Oral, 100

EQ 200 mg, Tartrate, Tablet, Extended Release, Oral, 100

FUL Decreases

Generic Name

FUL Price

Amiodarone Hydrochloride

200 mg, Tablet, Oral, 60

\$ 0.7375 R

Benzonatate

100 mg, Capsule, Oral, 100

\$ 0.1403 B

200 mg, Capsule, Oral, 100

\$ 0.2460 B

Betamethasone Dipropionate; Clotrimazole

EQ 0.05% Base/1%, Cream, Topical, 15

\$ 0.8230 B

FUL Decreases – continued

<u>Generic Name</u>	<u>FUL Price</u>
Citalopram Hydrobromide	
EQ 10 mg Base/5 ml, Solution, Oral, 240	\$ 0.3124 B
EQ 10 mg Base, Tablet, Oral, 100	\$ 0.1673 B
EQ 20 mg Base, Tablet, Oral, 100	\$ 0.1725 B
EQ 40 mg Base, Tablet, Oral, 100	\$ 0.1755 B
Clarithromycin	
500 mg, Tablet, Oral, 60	\$ 0.8625 B
Clobetasol Propionate	
0.05%, Cream, Topical, 30	\$ 0.1825 B
Methylphenidate Hydrochloride	
5 mg, Tablet, Oral, 100	\$ 0.2253 R
10 mg, Tablet, Oral, 100	\$ 0.3006 R
20 mg, Tablet, Oral, 100	\$ 0.3309 R
Naproxen	
250 mg, Tablet, Oral, 100	\$ 0.1032 B
375 mg, Tablet, Oral, 100	\$ 0.0761 B
500 mg, Tablet, Oral, 100	\$ 0.0824 B
Ofloxacin	
0.3%, Solution/Drops, Ophthalmic, 5	\$ 3.4500 B
Tizanidine Hydrochloride	
EQ 2 mg Base, Tablet, Oral, 150	\$ 0.2600 R
EQ 4 mg Base, Tablet, Oral, 150	\$ 0.3200 R

FUL Additions

<u>Generic Name</u>	<u>FUL Price</u>
Amoxicillin; Clavulanic Acid	
600 mg/5ml; EQ 42.9 mg Base/5 ml, Suspension, Oral, 75	\$ 0.4500 R
500 mg; EQ 125 mg Base, Tablet, Oral, 20	\$ 2.1158 B
875 mg; EQ 125 mg Base, Tablet, Oral, 20	\$ 2.5320 B

FUL Additions - continued

Generic Name

FUL Price

Clobetasol Propionate, Emollient Base
0.05%, Cream, Topical, 30

\$ 0.4465 B

These changes will be posted to our website at <http://www.cms.hhs.gov/Reimbursement>. If you have any questions, please contact Gail Sexton at gail.sexton@cms.hhs.gov, telephone number (410) 786-4583 or Meagan Khau at meagan.khau@cms.hhs.gov, telephone number (410) 786-1357.

/s/

Larry Reed
Director, Division of Pharmacy

cc: Regional Administrators



Center for Medicaid and State Operations

DATE: September 25, 2009

FROM: Director
Pharmacy Division

SUBJECT: Notification of Medicaid Drug Federal Upper Limit (FUL) Changes to
Transmittal No. 37, Dated November 20, 2001

TO: Associate Regional Administrators, Division of Medicaid and State Operations

Please inform the States in your region of the following FUL changes as soon as possible. The changes are to be implemented no later than October 26, 2009.

CMS used the following compendia sources in compiling this list:
B – Blue Book, M – Medi-Span, R – Red Book

FUL Decreases

<u>Generic Name</u>	<u>FUL Price</u>
Benzotropine Mesylate	
0.5 mg, Tablet, Oral, 100	\$ 0.0747 B
1 mg, Tablet, Oral, 100	\$ 0.0848 B
2 mg, Tablet, Oral, 100	\$ 0.1208 B
Carbamazepine	
200 mg, Tablet, Oral, 100	\$ 0.0849 B
Cephalexin	
EQ 250 mg, Capsule, Oral, 100	\$ 0.1650 B
EQ 500 mg, Capsule, Oral, 100	\$ 0.2730 B
Cyclobenzaprine Hydrochloride	
5 mg, Tablet, Oral, 100	\$ 0.1586 R
10 mg, Tablet, Oral, 100	\$ 0.1035 R
Diclofenac Potassium	
50 mg, Tablet, Oral, 100	\$ 0.4748 R

FUL Decreases – continued

<u>Generic Name</u>	<u>FUL Price</u>
Hydrochlorothiazide	
25 mg, Tablet, Oral, 1000	\$ 0.0180 B
50 mg, Tablet, Oral, 1000	\$ 0.0499 R
Ranitidine Hydrochloride	
EQ 15 mg Base/ml, Syrup, Oral, 473	\$ 0.2378 R
EQ 150 mg Base, Tablet, Oral, 100	\$ 0.0600 B
EQ 300 mg Base, Tablet, Oral, 30	\$ 0.1250 B

FUL Additions

<u>Generic Name</u>	<u>FUL Price</u>
Bicalutamide	
50 mg, Tablet, Oral, 100	\$ 3.4802 R
Cephalexin	
EQ 250 mg/5 ml, Suspension, Oral, 100	\$ 0.1818 R

These changes will be posted to our website at <http://www.cms.hhs.gov/Reimbursement>.
If you have any questions, please submit your inquiry to the following e-mail:
FUL@cms.hhs.gov

/s/

Larry Reed
Director, Division of Pharmacy

cc: Regional Administrators

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: July 15, 2009

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **decreased** in the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Decreases, Effective August 14, 2009

Drug Name	Brand Name	State MAC Rate
BRIMONIDINE TARTRATE 0.2 % DROPS	ALPHAGAN	1.68171
CEFDINIR 125 MG/5 ML SUSP RECON	OMNICEF	0.50890
CEFDINIR 250 MG/5 ML SUSP RECON	OMNICEF	1.09134
CEFDINIR 300 MG CAPSULE	OMNICEF	2.90319
DILTIAZEM HCL 120 MG CAPSULE CR	DILACOR XR	0.35862
DILTIAZEM HCL 180 MG CAP.SR 24H	CARDIZEM CD	1.00600
DILTIAZEM HCL 180 MG CAPSULE CR	DILACOR XR	0.36670
DILTIAZEM HCL 240 MG CAPSULE CR	DILACOR XR	0.41941
DILTIAZEM HCL 300 MG CAPSULE SA	TIAZAC	1.94617
DILTIAZEM HCL 60 MG TABLET	CARDIZEM	0.06695
ISOTRETINOIN 40 MG CAPSULE	ACCUTANE	5.94318

The following table lists State MAC rates to be **added** to the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate Additions, Effective August 14, 2009

Drug Name	Brand Name	State MAC Rate
DILTIAZEM HCL 120 MG CAP.SR 12H	CARDIZEM SR	1.04279
DILTIAZEM HCL 120 MG TABLET	CARDIZEM	0.13376
DILTIAZEM HCL 30 MG TABLET	CARDIZEM	0.03906
DILTIAZEM HCL 60 MG CAP.SR 12H	CARDIZEM SR	0.51968
DILTIAZEM HCL 90 MG CAP.SR 12H	CARDIZEM SR	0.73322
DILTIAZEM HCL 90 MG TABLET	CARDIZEM	0.09533
ISOTRETINOIN 10 MG CAPSULE	ACCUTANE	4.93616
ISOTRETINOIN 20 MG CAPSULE	ACCUTANE	5.19581

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on SMAC – State Maximum Allowable Cost Program. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: October 5, 2009

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **removed** from the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate **Terminations, Effective October 6, 2009**

Drug Name
ERYTHROMYCIN EYE OINTMENT

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate **Increases, Effective October 6, 2009**

Drug Name	Brand Name	State MAC Rate
ISOTRETINOIN 10 MG CAP	ACCUTANE	10.42996
ISOTRETINOIN 20 MG CAP	ACCUTANE	10.96063
ISOTRETINOIN 40 MG CAP	ACCUTANE	11.01859

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: October 19, 2009

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **removed** from the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Terminations, Effective October 26, 2009

Drug Name
HYDROCHLOROTHIAZIDE 50 MG TABLET
RANITIDINE HYDROCHLORIDE 150 MG TABLET

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: October 27, 2009

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **added** to the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Additions, Effective November 25, 2009

Drug Name	Brand Name	State MAC Rate
BICALUTAMIDE 50 MG TAB	CASODEX	3.01998

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: January 27, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists the State MAC rate to be **removed from** the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Termination, Effective January 30, 2010

Drug Name
ERYTHROMYCIN EYE OINTMENT

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: February 2, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **added** to the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Additions, Effective March 4, 2010

Drug Name	Brand Name	State MAC Rate
ACYCLOVIR 200 MG/5 ML SUSP	ZOVIRAX	0.21356
CEFPODOXIME 100 MG/5 ML SUSP ECON	VANTIN	0.81737
CYCLOSPORINE 100 MG/ML SOLN	NEORAL	3.94668
DIVALPROEX SODIUM ER 250 MG TAB	DEPAKOTE ER	0.42036
DIVALPROEX SODIUM ER 500 MG TAB	DEPAKOTE ER	0.56503
LANSOPRAZOLE 30 MG CAPSULE DR	PREVACID	2.46988
MYCOPHENOLATE 250 MG CAPSULE	CELLCEPT	0.44518
NATEGLINIDE 120 MG TABLET	STARLIX	1.18110
NATEGLINIDE 60 MG TABLET	STARLIX	1.27954
RISPERIDONE 1 MG/ ML SOLUTION	RISPERDAL	1.19084
ZALEPLON 5 MG CAP	SONATA	0.37639
ZALEPLON 10 MG CAP	SONATA	0.38708

The following table lists State MAC rates to be **decreased** in the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate Decreases, Effective March 4, 2010

Drug Name	Brand Name	State MAC Rate
AZITHROMYCIN 500 MG TAB	ZITHROMAX	2.89200
CYCLOSPORINE 100 MG SOFTGEL	NEORAL	2.80074
CYCLOSPORINE 25 MG SOFTGEL	NEORAL	0.75960
METOPROLOL SUCC ER 25 MG TAB	TOPROL XL	0.82500
METOPROLOL SUCC ER 50 MG TAB	TOPROL XL	0.84228
MYCOPHENOLATE 500 MG TABLET	CELLCEPT	0.92531

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

Drug Name	Brand Name	State MAC Rate
OMEPRAZOLE 20 MG CAP	PRILOSEC	0.18035
OMEPRAZOLE 40 MG CAP DR	PRILOSEC	0.42288
OXYCODONE/APAP 5/325 MG TAB	PERCOCET	0.04631
RISPERIDONE 0.25MG TAB	RISPERDAL	0.35288
RISPERIDONE 0.5MG TAB	RISPERDAL	0.38994
RISPERIDONE 1MG TAB	RISPERDAL	0.40357
RISPERIDONE 2MG TAB	RISPERDAL	0.41286
RISPERIDONE 3MG TAB	RISPERDAL	0.46044
RISPERIDONE 4MG TAB	RISPERDAL	0.62112
SUMATRIPTAN SUCC 100 MG TAB	IMITREX	2.14248
SUMATRIPTAN SUCC 25 MG TAB	IMITREX	2.31263
SUMATRIPTAN SUCC 50 MG TAB	IMITREX	2.13766

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: February 19, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Increases, Effective February 23, 2010

Drug Name	Brand Name	State MAC Rate
DESONIDE 0.05% LOT	DESOWEN	.53074

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: March 24, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **added** to the State MAC Program. The legend benzoyl peroxide products will temporarily be made preferred with the applicable SMAC reimbursement only until the OTC versions become available.

Table 1: Iowa Medicaid State MAC Rate Additions, Effective March 23, 2010

Drug Name	Brand Name	State MAC Rate
BENZOYL PEROXIDE 10 % CLEANSER	DESQUAM-X	0.09797
BENZOYL PEROXIDE 10% GEL	BENZAC	0.22966
BENZOYL PEROXIDE 5 % CLEANSER	BENZAC W WASH	0.10103
BENZOYL PEROXIDE 5 % GEL ALCOHL	BENZAGEL-5	0.24154
BENZOYL PEROXIDE 5% GEL	BENZAC	0.22958

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: April 19, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate **Increases, Effective April 23, 2010**

Drug Name	Brand Name	State MAC Rate
ACETAMINOPHEN/COD 300/30MG TAB	TYLENOL W/CODEINE	0.14206
ALBUTEROL 0.83 MG/ML SOLN	PROVENTIL/VENTOLIN	0.08551

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

100 ARMY POST ROAD - DES MOINES, IA 50315-6257

Page 1 of 1

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: April 07, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Increases, Effective April 23, 2010

Drug Name	Brand Name	State MAC Rate
BETAMETHASONE DP 0.05% AUGMTD OINT	DIPROLENE	3.21792

The following table lists State MAC rates to be **removed from** the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate Terminations, Effective April 23, 2010

Drug Name	Brand Name
TRIAMTERENE/HCTZ 50/25 MG CAP	DYAZIDE

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

100 ARMY POST ROAD - DES MOINES, IA 50315-6257

Page 1 of 1

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: April 07, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate **Increases**, Effective April 23, 2010

Drug Name	Brand Name	State MAC Rate
BETAMETHASONE DP 0.05% AUGMTD OINT	DIPROLENE	3.21792

The following table lists State MAC rates to be **removed from** the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate **Terminations**, Effective April 23, 2010

Drug Name	Brand Name
TRIAMTERENE/HCTZ 50/25 MG CAP	DYAZIDE

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

100 ARMY POST ROAD - DES MOINES, IA 50315-6257

Page 1 of 1

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: April 21, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **added** to the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Additions, Effective May 21, 2010

Drug Name	Brand Name	State MAC Rate
AMPHETAMINE SALTS 15 MG TAB	ADDERALL	0.36108
DRONABINOL 2.5 MG CAP	MARINOL	3.32040
FEXOFENADINE-PSE ER 60 - 120 HOUR TABLET	ALLEGRA-D 12 HOUR	1.63270
FLUPHENAZINE DEC 25 MG/ML VIAL	PROLIXIN	11.35860
SUMATRIPTAN SUCCINATE 6 MG/0.5 ML SYRNG KIT	IMITREX	166.13200
VANCOMYCIN 1 GM VIAL	VANCONIN	6.10848

The following table lists State MAC rates to be **decreased** in the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate Decreases, Effective May 21, 2010

Drug Name	Brand Name	State MAC Rate
AMLODIPINE BESYLATE 10 MG TAB	NORVASC	0.04847
AMOXICILLIN 250 MG/5 ML SUSP	AMOXIL	0.03020
AMPHETAMINE SALTS 10 MG TAB	ADDERALL	0.17044
AMPHETAMINE SALTS 20 MG TAB	ADDERALL	0.17543
ATENOLOL 25 MG TAB	TENORMIN	0.01927
BENZTROPINE MES 1 MG TAB	COGENTIN	0.04854
BUPROPION HCL SR 150 MG TAB -	WELLBUTRIN SR	0.48173
BUPROPION XL 150MG TAB	WELLBUTRIN XL	0.95783
BUSPIRONE HCL 15 MG TAB	BUSPAR	0.07511
CEFDINIR 125 MG/5 ML SUSP	OMNICEF	0.36100
CEFDINIR 250 MG/5 ML SUSP	OMNICEF	0.62537

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

100 ARMY POST ROAD - DES MOINES, IA 50315-6257

Page 1 of 3

Decreases Effective May 21, 2010 Cont'd

Drug Name	Brand Name	State MAC Rate
CEFDINIR 300 MG CAP	OMNICEF	1.50856
CLONIDINE HCL 0.2 MG TAB	CATAPRES	0.04861
DIAZEPAM 10 MG TAB	VALIUM	0.02563
DIVALPROEX SODIUM 250 MG TAB D	DEPAKOTE	0.08616
DOXYCYCLINE 100 MG CAP	VIBRAMYCIN	0.05129
DOXYCYCLINE HYCLATE 100 MG TAB	VIBRAMYCIN	0.06043
DRONABINOL 10 MG CAPSULE	MARINOL	15.61300
DRONABINOL 5 MG CAPSULE	MARINOL	7.54370
ETH ESTRADIOL/LEVONOR 20MCG/0.	ALESSE	0.68234
FAMOTIDINE 20 MG TAB	PEPCID	0.04074
FENTANYL 100 MCG/HR PATCH	DURAGESIC	26.38583
FENTANYL 25 MCG/HR PATCH	DURAGESIC	7.20758
FENTANYL 50 MCG/HR PATCH	DURAGESIC	12.45854
FENTANYL 75 MCG/HR PATCH	DURAGESIC	21.06444
FLUOXETINE 20 MG CAP	PROZAC	0.02470
FLUTICASONE 50 MCG NASAL SPRAY	FLONASE	0.36397
FOLIC ACID 1 MG TAB	FOLACIN / APO-FOLIC	0.01368
GLYBURIDE 5 MG TAB	MICRONASE	0.04856
IBUPROFEN 100 MG/5 ML SUSP	MOTRIN	0.02551
IBUPROFEN 600 MG TAB	MOTRIN	0.02446
LEVETIRACETAM 100 MG/ML SOLN	KEPPRA	0.13368
LITHIUM CARBONATE 300 MG CAP	ESKALITH	0.04019
METFORMIN HCL 1000 MG TAB	GLUCOPHAGE	0.04746
METHIMAZOLE 5 MG TAB	TAPAZOLE	0.18652
MORPHINE SULF 30 MG TAB SA	MS CONTIN	0.36030
MORPHINE SULF 60 MG TAB SA	MS CONTIN	0.61067
NABUMETONE 500 MG TAB	RELAFEN	0.27347
NABUMETONE 750 MG TAB	RELAFEN	0.30766
NYSTATIN 100,000 UNIT/ML SUSP	MYCOSTATIN	0.04489
OXCARBAZEPINE 150 MG TAB	TRILEPTAL	0.27216
OXCARBAZEPINE 300 MG TAB	TRILEPTAL	0.44704
OXCARBAZEPINE 600 MG TAB	TRILEPTAL	0.85879
OXYBUTYNIN 5 MG TAB	DITROPAN	0.04352
OXYCODONE HCL 15 MG TAB	ROXICODONE	0.23741
OXYCODONE/APAP 10/325 MG TAB	PERCOCET	0.41330
OXYCODONE/APAP 7.5/325 MG TAB	PERCOCET	0.34345
PHENYTOIN SOD EXT 100 MG CAP	DILANTIN	0.16530
PROMETHAZINE 25 MG TAB	PHENERGAN	0.14951
PROMETHAZINE/CODEINE SYRP	PHENERGAN W/CODEINE	0.01283
RISPERIDONE 0.25MG TAB	RISPERDAL	0.29292

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Decreases Effective May 21, 2010 Cont'd

Drug Name	Brand Name	State MAC Rate
RISPERIDONE 0.5MG TAB	RISPERDAL	0.26578
RISPERIDONE 1MG TAB	RISPERDAL	0.29095
RISPERIDONE 2MG TAB	RISPERDAL	0.35638
RISPERIDONE 3MG TAB	RISPERDAL	0.39982
ROPINIROLE HCL 0.5 MG TAB	REQUIP	0.35976
ROPINIROLE HCL 1 MG TAB	REQUIP	0.35542
ROPINIROLE HCL 2 MG TAB	REQUIP	0.36300
SULFAMETHOXAZOLE/TMP DS TAB	SEPTRA	0.07742
VENLAFAXINE HCL 75 MG TAB	EFFEXOR	0.39955
WARFARIN SODIUM 5 MG TAB	COUMADIN	0.09043
ZOLPIDEM TARTRATE 10 MG TAB	AMBIEN	0.03598
ZONISAMIDE 100 MG CAP	ZONEGRAN	0.14122

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 3: Iowa Medicaid State MAC Rate Increases, Effective May 5, 2010

Drug Name	Brand Name	State MAC Rate
AMOXICILLIN 125 MG/5 ML SUSP	AMOXIL	0.02591
CARBAMAZEPINE 100 MG/5 ML SUSP	TEGRETOL	0.11290
GABAPENTIN 100 MG CAP	NEURONTIN	0.05674
GABAPENTIN 300 MG CAP	NEURONTIN	0.10296
GABAPENTIN 400 MG CAP	NEURONTIN	0.12342
SULFAMETHOXAZOLE/TMP SUSP	SEPTRA	0.04631

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise. This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.

100 ARMY POST ROAD - DES MOINES, IA 50315-6257

Page 3 of 3

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: May 20, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **increased** in the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate Increases, Effective May 28, 2010

Drug Name	Brand Name	State MAC Rate
FLUTICASONE 50 MCG NASAL SPRAY	FLONASE	2.01391

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on SMAC – State Maximum Allowable Cost Program. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Iowa Medicaid Enterprise

Revisions to the State Maximum Allowable Cost (State MAC) Program for Multi-Source Prescription Drugs

Notification Date: May 21, 2010

This letter provides notification of the increases, decreases, additions and removal of State MAC rates to the Iowa Medicaid State MAC program.

Iowa Medicaid State Maximum Allowable Cost (State MAC) Program

The following table lists State MAC rates to be **added** to the State MAC Program:

Table 1: Iowa Medicaid State MAC Rate **Additions, Effective June 20, 2010**

Drug Name	Brand Name	State MAC Rate
AMOX TR-K CLV 250-62.5/5 SUSP	AUGMENTIN	0.74386
DEFEROXAMINE 2 GM VIAL	DESFERAL	39.31500
DEFEROXAMINE 500 MG VIAL	DESFERAL	10.13400
GRISEOFULVIN 125 MG/5 ML SUSP	GRIFULVIN V	0.12830
HALOPERIDOL 10 MG TAB	HALDOL	0.83539
HYDROMORPHONE HCL 8 MG TAB	DILAUDID	0.74987
KETOROLAC 0.4% OPTH SOLUTION	ACULAR LS	2.36369
KETOROLAC 0.5% OPTH SOLUTION	ACULAR	3.81748
PRAMIPEXOLE DI-HCL 0.125 MG TAB	MIRAPEX	2.56514
TEMAZEPAM 7.5 MG CAP	RESTORIL	6.61009

The following table lists State MAC rates to be **decreased** in the State MAC Program:

Table 2: Iowa Medicaid State MAC Rate **Decreases, Effective June 20, 2010**

Drug Name	Brand Name	State MAC Rate
AMOX TR-K CLV 200-28.5 MG/5ML	AUGMENTIN	0.16242
AMOX TR-K CLV 400-57 MG/5 ML S	AUGMENTIN	0.20617
AZITHROMYCIN 200 MG/5 ML SUSP	ZITHROMAX	0.90289
AZITHROMYCIN 250 MG TAB	ZITHROMAX	0.77425
AZITHROMYCIN 500 MG TAB	ZITHROMAX	1.57289
BUPROPRIION XL 300 MG TAB	WELLBUTRIN XL	1.18204
HYDROXYZINE 10 MG/5 ML SYRP	ATARAX	0.06346
IPRATR-ALBUTEROL 0.5-3 MG/3 ML	DUONEB	0.10746
LEVETIRACETAM 500 MG TAB	KEPPRA	0.29909
LEVOTHYROXINE 50 MCG TAB	SYNTHROID	0.09925
LORAZEPAM 2 MG/ML ORAL CONCENT	LORAZEPAM	1.10000

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Decreases cont'd

Drug Name	Brand Name	State MAC Rate
METHYLPHENIDATE 10 MG TAB	RITALIN	0.08654
METHYLPHENIDATE 20 MG TAB	RITALIN	0.13672
METHYLPHENIDATE 20 MG TAB SA	CONCERTA	0.26172
METHYLPHENIDATE 5 MG TAB	RITALIN	0.06042
OXYCODONE HCL 5 MG TAB	ROXICODONE	0.12305
RANITIDINE 150 MG TAB	ZANTAC	0.02708
RANITIDINE 150 MG/10 ML SYRP	ZANTAC	0.10057
SUMATRIPTAN SUCC 100 MG TAB	IMITREX	1.73212
SUMATRIPTAN SUCC 25 MG TAB	IMITREX	1.81768
SUMATRIPTAN SUCC 50 MG TAB	IMITREX	1.72174

Future Notification of Revisions to the State MAC Program

Notification for revisions to the State MAC program that are made in between annual pharmacy acquisition cost surveys will be posted to the IME website (www.ime.state.ia.us) prior to the effective date of the changes. To access the list, please go to **Quick Links** and click on **SMAC – State Maximum Allowable Cost Program**. Revisions include the addition of new State MAC rates, increases and decreases of current State MAC rates, or termination of current State MAC rates. Providers are advised to access the State MAC website regularly to review these revisions.

If you would like to receive email notification of these revisions to the State MAC program, please send your email address to pharmacy@mslc.com.

*This publication provides information to Pharmacy providers who submit claims to Iowa Medicaid Enterprise.
This bulletin should be shared with all health care practitioners and managerial members of the pharmacy store staff.*

Appendix J

Newsletters

2009

Vol. 22, No. 1

DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review in Iowa

DUR Commission Members

Bruce Alexander, R.Ph., Pharm.D.,
BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.
Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D.,
BCPS
Susan Parker, Pharm.D.
Laurie Pestel, Pharm.D.
Richard M. Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

DUR Professional Staff

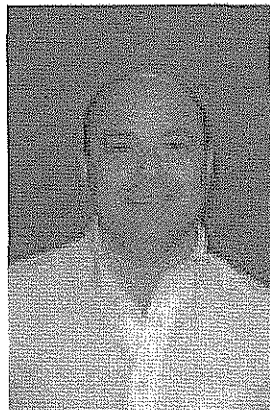
Thomas Kline, D.O.
IME Medical Director

Pamela Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, R.Ph., Pharm.D.

COMMISSION WELCOMES NEW MEMBERS

Dr. Casey Clor, M.D. and Larry Ambrosion, R.Ph. have been named as the newest members of the Iowa Medicaid Drug Utilization Review Commission. The Commission and the Department of Human Services welcomes both Dr. Clor and Larry and look forward to working with them throughout their four-year term.



Dr. Clor has been a family practice physician at the Mercy East Family Practice clinic since completing his residency at the Mercy/Mayo Family Practice Residency Program in Des Moines. Dr. Clor also holds Masters of Pharmacy Sciences. In addition to family medicine, Dr. Clor has experience in emergency medicine, has served as the Assistant Director for the Mercy Center for Weight Reduction, as well as serving as part of the adjunct faculty for Des Moines University. He currently is serving on the Governor's Council on Physical Fitness and Nutrition. Dr. Clor was appointed to the DUR Commission in 2009; his first term will expire in 2013.



Larry Ambrosion currently owns and operates The Medicine Shoppe Pharmacy in Newton, Iowa. Before returning to Iowa, Larry worked as a staff pharmacist for Columbia Regional Hospital in Columbia, Missouri. In addition to running his business, Larry also sits on a review board with Capstone Health in Newton. Larry was appointed to the DUR Commission in 2009; his first term will expire in 2013.

In the Spotlight: Anti-Acne Prior Authorization Criteria

Prior authorization is required for all prescription topical acne products for the treatment of mild to moderate acne vulgaris. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. An initial treatment failure of an over-the-counter benzoyl peroxide product, which is covered by the program, is required prior to the initiation of a prescription product, or evidence must be provided that use of these agents would be medically contraindicated. If the patient presents with a preponderance of comedonal acne, tretinoin products may be utilized as first line agents with prior authorization.

Iowa Medicaid does not cover duplicate topical anti-acne prescription products. The member must have an unsuccessful trial of at least 4 to 6 weeks with each product alone before duplicate topical therapy can be considered. You can find a list of payable OTC benzoyl peroxide products at iowamedicaidpdl.com on the OTC Payable List by NDC found under the Preferred Drug Lists link.

Palivizumab (Synagis) PA Criteria Update

2009-2010 RSV Season

For the 2009-2010 RSV Season, Iowa Medicaid will **NOT** be adopting the 2009 *Red Book* modified recommendations for use of palivizumab for prevention of respiratory syncytial virus (RSV) and will follow the same clinical criteria as the 2008-2009 RSV season. This year, PA's will be approved with a **start date of November 16th** and will be valid through March 2010. A **maximum of 5 doses** will be allowed. PA's will be approved for a 30 day supply with a quantity limit of one-50 mg vial and two-100 mg vials per month. The Palivizumab (Synagis) PA form can be found online at iowamedicaidpdl.com under PA forms.

Criteria for the 2009-2010 RSV Season

Prior authorization is required for therapy with palivizumab. Payment for palivizumab will be considered for patients who meet one of the following criteria:

Chronic Lung Disease (CLD)

- Patient is less than 24 months of age at start of therapy and has chronic lung disease of prematurity (i.e. bronchopulmonary dysplasia) requiring medication (bronchodilator, corticosteroid, or diuretic therapy) or oxygen within six months before the anticipated start of RSV season.

Prematurity

- Patient is less than 12 months of age at start of therapy with a gestational age of less than or equal to 28 weeks.
- Patient is less than 6 months of age at start of therapy with a gestational age between 28 weeks and 31 weeks.
- Patient is less than 6 months of age at start of therapy with a gestational age of 32 weeks to 35 weeks and has at least two risk factors.

Congenital Heart Disease (CHD)

- Patient is less than 24 months of age at start of therapy and has hemodynamically significant congenital heart disease further defined by any of the following: Receiving medication to control congestive heart failure, moderate to severe pulmonary hypertension, or cyanotic congenital heart disease.

Severe Immunodeficiency

- Patient is less than 24 months of age at start of therapy and has severe immunodeficiencies (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome).

DUR Activities

- The Commission reported back on a focus study that encouraged high utilizers of triptans for migraines to consider switching to a prophylactic medication instead. This activity resulted in a cost savings of \$41,357.07 (pre-rebate; state and federal).
- The Commission reported back on a focus study on chronic Bactroban/Mupirocin use that resulted in a cost savings of \$11,156.41 (pre-rebate; state and federal dollars).
- The Commission reported back on a focus study that looked at duplicate SSRIs which resulted in a cost savings of \$8,723.49 (pre-rebate; state and federal dollars).
- The Commission reported back on a focus study that looked at combining long acting narcotics with methadone which resulted in a cost savings of \$2,081.70 (pre-rebate; state and federal dollars).
- The Commission developed new clinical PA criteria for febuxostat (*Uloric*).

Medicaid Statistics for Prescription Claims from April 1, 2009 to June 30, 2009

Top Drugs by Number of Prescriptions	Top Drugs by Dollars Spent	Top Therapeutic Class by Dollars Spent
<i>ProAir HFA</i> \$44.28/Rx	<i>Lexapro 20mg</i> \$826,001	Antipsychotics – Atypicals \$10.9 million
Hydrocodone/APAP 5-500 \$5.58/Rx	<i>Abilify 5mg</i> \$817,278	Anticonvulsants \$5.5 million
<i>Lexapro 20mg</i> \$84.61/Rx	<i>Adderall XR 20mg</i> \$822,408	Antidepressants – Selected SSRI's \$4.2 million
Loratadine 10mg 8.55/RX	<i>Abilify 10mg</i> \$783,049	Stimulants – Amphetamines – Long Acting \$3.5 million
Ferrous Sulfate 325mg \$4.33/RX	Concerta 36mg \$805,381	Stimulants – Methylphenidate- Long Acting \$2.3 million

Average amount paid per claim: \$63.58

Number of claims paid: 978,425

Average amount paid per claim, brand: \$187.65

Percent controlled substances: 18.82%

Total dollars paid: \$62,497,731.53



Iowa Medicaid Drug Utilization Review
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

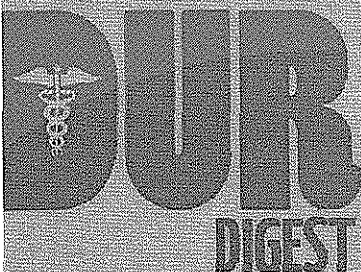
PRSRT STD
U.S. POSTAGE
PAID
DES MOINES, IA
PERMIT NO. 1195

Did you know...

- ❖ **Zyvox interaction** - Zyvox (linezolid) is a reversible nonselective inhibitor of monoamine oxidase and therefore has the potential to interact with serotonergic and adrenergic agents. Zyvox therapy should be avoided in patients who have carcinoid syndrome and/or are taking serotonergic agents such as serotonin reuptake inhibitors, tricyclic antidepressants, serotonin 5-HT 1 receptor agonists (triptans), meperidine, and buspirone. Unless patients are monitored for increases in blood pressure, Zyvox should not be given to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis and/or patients taking directly and indirectly acting sympathomimetic agents (pseudoephedrine), vasopressive agents (epinephrine, norepinephrine), or dopaminergic agents (dopamine, dobutamine). Zyvox is approved for the treatment of infections caused by designated strains of susceptible microorganisms. Specific indications include vancomycin-resistant *Enterococcus faecium* infections, nosocomial pneumonia, community-acquired pneumonia, and complicated and uncomplicated skin or skin structure infections. Zyvox is a preferred agent on the Preferred Drug List, but does require a prior authorization.
- ❖ **FDA Website for Healthcare Professionals** - The FDA has recently updated their website for healthcare professionals to support patient safety. Doctors, pharmacists, nurses, and other healthcare professionals can visit www.fda.gov/healthprofessionals for access to reporting adverse events or to find new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed."
- ❖ **MDI's vs. Inhalation Solution** - According to the evidence-based guidelines published by the American College of Chest Physicians and the American College of Asthma, Allergy, and Immunology, efficacy should not be the basis for selecting one inhalation delivery device over another, as inhalation delivery devices have been found to be equally effective. There is a significant cost difference between inhalation solutions and metered dose inhalers. Where possible, MDIs should be used as they are the most cost effective. Spacers are covered as DME.

2010

Vol. 22, No. 2



**The Bulletin of
Medicaid Drug
Utilization Review
in Iowa**

DUR Commission Members

Bruce Alexander, R.Ph., Pharm.D.,
BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.
Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D.,
BCPS
Susan Parker, Pharm.D.
Laurie Pestel, Pharm.D.
Richard M. Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

DUR Professional Staff

Thomas Kline, D.O.
IME Medical Director

Pamela Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, R.Ph., Pharm.D.

Recommendation Regarding ECG Monitoring in Patients on Methadone by the CSAT

In January, 2009, the following recommendation was issued: The Center for Substance Abuse and Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration has developed a consensus guideline statement outlining recommendations regarding ECG monitoring in patients being considered for and being treated with methadone regardless of indication. Of note, these recommendations should not supersede clinical judgment or patient preferences and may not apply to patients with terminal, intractable cancer pain.

Five recommendations have been developed:

Recommendation 1 [Disclosure]: Clinicians should inform patients of arrhythmia risk when methadone is prescribed.

Recommendation 2 [Clinical History]: Clinicians should inquire about any history of structural heart disease, arrhythmia, and syncope.

Recommendation 3 [Screening]: Clinicians should obtain pretreatment ECG for all patients to measure QTc interval, follow up ECG within 30 days, then annually (monitor more frequently if patient receiving >100 mg/day or if unexplained syncope or seizure occurs while on methadone).

Recommendation 4 [Risk Stratification]: If before or at anytime during therapy:

QT_c >450-499 msec: Discuss potential risks and benefits; monitor QT_c more frequently

QT_c ≥500 msec: Consider discontinuation or reducing methadone dose or eliminate factors promoting QT_c prolongation (eg, potassium-wasting drugs) or use alternative therapy (eg, buprenorphine)

Recommendation 5 [Drug Interactions]: Clinicians should be aware of interactions between methadone and other drugs that either prolong the QT interval or reduce methadone elimination.

The panel also concluded that the arrhythmia risk is directly associated with methadone's ability to block the delayed rectifier potassium channel (I_{kr}) and prolong repolarization. The guideline further states that the use of the Bazett formula is adequate even though it is likely to overcorrect with high heart rates. The patient should remain supine for at least 5 minutes prior to obtaining ECG. In addition, screening for QT_c prolongation using automated readings does not require a specialist (eg, cardiologist) and may be performed in a primary care setting. However, in cases when uncertainty exists about whether or not clinically significant QT_c prolongation is present, the ECG should be repeated or interpreted by a cardiologist.

Methadone is a preferred drug on the Iowa Medicaid PDL. Other preferred options within the long acting narcotics PDL category include morphine sulfate ER, Kadian®, and Avinza®. No PA is required, but quantity limits do apply.

Krantz MJ, Martin J, Stimmel B, et al, "QT_c Interval Screening in Methadone Treatment," *Ann Int Med*, 2009, 150(1):1-10.

Clinical Information

- At a recent meeting of the American Society of Clinical Oncology, two observational studies were presented looking at the effect of strong CYP2D6 inhibitors in patients taking tamoxifen in preventing recurrence of breast cancer. One of these two studies found that women who took CYP2D6 inhibitors, such as SSRIs, had a higher recurrence rate. Tamoxifen is a prodrug that requires metabolism by CYP2D6 to its active metabolite. SSRIs such as fluoxetine and paroxetine are potent inhibitors of CYP2D6. Sertraline is a moderate inhibitor of CYP2D6, and citalopram and escitalopram are less potent inhibitors of CYP2D6. Since there is no good evidence that one SSRI is more effective than another for treating depression, citalopram or escitalopram may be the safest choice for women that are taking tamoxifen and need to start an SSRI.
- The FDA is reminding health care professionals about the increased risk of neural tube defects and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy. The FDA will be working with the manufacturers of these products to address labeling changes. Healthcare practitioners should inform women of childbearing potential about these risks, and consider alternative therapies, especially if using valproate to treat migraines or other conditions not usually considered life-threatening. Women of childbearing potential should only use valproate if it is essential to manage their medical condition. Those who are not actively planning a pregnancy should use effective contraception, as birth defect risks are particularly high during the first trimester, before many women know they are pregnant.

Preferred Drug List (PDL) Information

- **Antihistamines:** Patients 21 years of age and older must have three unsuccessful trials with antihistamines that do not require prior authorization, prior to the approval of a non-preferred first generation or preferred second generation antihistamine. Two of the trials must be with cetirizine and loratadine. Patients 20 years of age and younger must have unsuccessful trials with cetirizine and loratadine prior to approval of a non-preferred first generation or preferred second generation prescription antihistamine.
- **Muscle Relaxants:** Requests for carisoprodol will be approved for a maximum of 120 tablets per 180 days at a maximum dose of 4 tablets per day when the criteria for coverage are met.
- The following generics are now preferred over the brand name: bupropion XL (*Wellbutrin XL*), ipratropium bromide/albuterol (*Duoneb*), medroxyprogesterone acetate IM (*Depo-Provera*), nifedipine ER (*Adalat CC*), norethindrone & ethinyl estradiol 1/35 (*Ortho-Novum 1/35*), ranitidine syrup (*Zantac Syrup*), sumatriptan (*Imitrex*), topiramate (*Topamax*), venlafaxine ER (*Effexor XR*).

- The Commission reported back on a focus study looking at duplicate inhaled anticholinergics. As a result of the intervention, the Commission reported a total cost savings of \$60,629.33 (State & Federal Dollars, pre-rebate) over a three month time frame.
- The Commission mailed out the first Quarterly Narcotic Utilization Report to Prescribers in September 2009. It is important for pharmacies to enter the correct prescriber information. Several phone calls were made to Iowa Medicaid by prescribers stating they do not have record of treating a listed member. The most common reason for this was incorrect information entered by the pharmacy. Prescribers need to contact the listed dispensing pharmacy to correct the information as Iowa Medicaid cannot correct this. Prescribers also need to keep their information current with Iowa Medicaid by contacting Prescriber Services any time their information changes. Provider Services can be reached at 1-800-338-7909 or 515-725-1004.

Medicaid Statistics for Prescription Claims

from October 1, 2009 to December 31, 2009

Number of claims paid: 1,073,953

Average amount paid per claim: \$59.81

Total dollars paid: \$64,236,696.20

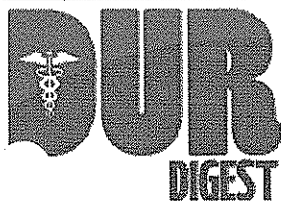
Average amount paid per claim, brand: \$184.52

Percent controlled substances: 18.67%

Average Amount paid per claim, generic: \$13.09

Top Drugs by Number of Prescriptions*	Top Drugs by Dollars Spent (Pre-Rebate)	Top Therapeutic Class by Dollars Spent (Pre-Rebate)
<i>ProAir HFA</i> \$43.15/Rx	Synagis 100mg/ml \$1.1 million	Antipsychotics – Atypicals \$10.6 million
Hydrocodone/APAP 5-500 \$5.27/Rx	Concerta 36mg \$950,121	Anticonvulsants \$4.3 million
<i>Lexapro 20mg</i> \$82.05/Rx	<i>Adderall XR 20mg</i> \$936,561	Antidepressants – Selected SSRI's \$4.2 million
Cheratussin AC \$6.14/RX	<i>Abilify 5mg</i> \$900,442	Stimulants – Amphetamines – Long Acting \$3.9 million
Loratadine 10mg \$7.37/RX	<i>Lexapro 20mg</i> \$840,780	Stimulants – Methylphenidate-Long Acting \$2.6 million

*Reported cost per prescription is pre-rebate



Iowa Medicaid Drug Utilization Review
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

PRSR STD
U.S. POSTAGE
PAID
DES MOINES, IA
PERMIT NO. 1195

Annual Call for New Commission Member

Attention Pharmacists: Are you looking for a new professional opportunity?

CMS requires state Medicaid programs to have a drug utilization review (DUR) program consisting of prospective DUR, retrospective DUR, and an educational program. The goal of the DUR program is to ensure appropriate medication therapy, while permitting appropriate professional judgment to individualize medication therapy. In Iowa, the DUR Board is referred to as the Iowa Medicaid DUR Commission. The Iowa DUR Commission is composed of four Iowa licensed physicians and four Iowa licensed pharmacists who serve four-year terms, as well as a representative from the Department of Human Services. The Commission meets on the first Wednesday six months of the year from 9:30 a.m. to 1:30 p.m.

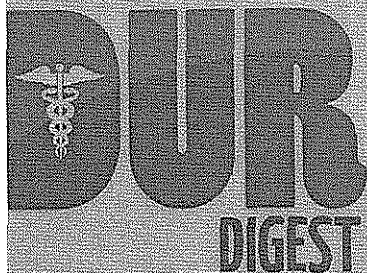
The DUR Commission is currently seeking a Pharmacist who serves Medicaid members to join the committee. Any Pharmacist interested in serving in this capacity should send a resume or curriculum vitae, as well as a letter indicating their interest to Pam Smith at the address shown below. Candidates that would like more information about the Commission or who would like to speak to a present Commissioner are encouraged to call.

The deadline for applications is May 1, 2010.

Pam Smith, R.Ph.
DUR Project Coordinator
Iowa Medicaid Drug Utilization Review Commission
100 Army Post Road
Des Moines, IA 50315
(515) 974-3131
info@iadur.org

2010

Vol. 22, No. 3



**The Bulletin of
Medicaid Drug
Utilization Review
in Iowa**

DUR Commission Members

Bruce Alexander, R.Ph., Pharm.D.,
BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.
Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D.,
BCPS
Susan Parker, Pharm.D.
Laurie Pestel, Pharm.D.
Richard M. Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

DUR Professional Staff

Thomas Kline, D.O.
IME Medical Director

Pamela Smith, R.Ph.
DUR Project Coordinator

Shad Bissell, R.Ph., Pharm.D.

Drugs for Dementia

Dementia comes in many different forms, with Alzheimer's disease (AD) being the most common. Acetylcholinesterase inhibitors (donepezil, galantamine, rivastigmine and tacrine) inhibit the enzyme that breaks down acetylcholine, thus increasing its concentration in the brain, which may have a beneficial effect on the symptoms of dementia. Acetylcholinesterase inhibitors carry with them a common adverse effect profile seen with cholinergic medications, such as bradycardia, syncope, nausea, vomiting and diarrhea. These adverse effects seem to be most common with initiation of therapy and when the dose is increased. The mechanism of action for the *N*-methyl-D-aspartate (NMDA)-receptor antagonist, memantine, is unknown. It is postulated that it blocks the amino acid glutamate, which contributes to the symptoms of AD. Common adverse effects include dizziness, confusion, hallucinations, delusions and insomnia.

The acetylcholinesterase inhibitors, Aricept® (donepezil) and Exelon® (rivastigmine), and the NMDA-receptor antagonist, Namenda® (memantine), currently do not require a Prior Authorization but are restricted to patients 40 years of age and older.

Aricept® (donepezil) is FDA approved for treatment of mild-to-moderate AD, Exelon® (rivastigmine) is FDA approved for treatment of mild to moderate dementia associated with AD or Parkinson's disease, and Namenda® (memantine) is FDA approved for the treatment of moderate-to-severe AD. Although FDA approved for Alzheimer's, additional studies performed have questioned these drugs' efficacy. A meta-analysis published by Raina et al reviewed 20 years of English language randomized, controlled trials evaluating all cholinesterase inhibitors and memantine. A total of 96 publications and 59 discrete studies were included in this review. Their conclusions were that all agents used to treat dementia provide statistically significant yet clinically marginal outcomes in terms of improved cognition.² A 2008 clinical practice guideline co-authored by the American College of Physicians and the American Academy of Family Physicians, reviewed the current five drug treatment options for dementia. In addition to reporting results on the statistical significance of trials, the guideline panel assessed clinically important effects of treatment regimens, as measured by generally-accepted magnitudes of changes in tools used to measure cognition defects. As in Raina's review, the guideline panel found statistical significance without uniform clinical significance, and lack of convincing evidence demonstrating superiority of one therapeutic treatment over another.³

When prescribing these medications, consideration must be given to the significant cost of the medication and the adverse effects caused by these medications. If patients have not responded to therapy three months after initiation of therapy, the medication should be stopped. It should also be noted that these medications do not stop or reverse the progression of AD.

References:

1. American Psychiatric Association Diagnostic and Statistical Manual, 4th ed, APA Press, Washington DC, 1994.
2. Raina P, Santaguida P, Ismail A et al. Effectiveness of cholinesterase inhibitors and memantine for treating dementia: evidence review for a clinical practice guideline. *Ann Intern Med* 2008 Mar 04; 148(5): 379-97.
3. Qaseem A, Snow V, Cross JT Jr et al. Current pharmacologic treatment of dementia: a clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians. *Ann Intern Med* 2008 Mar 04; 148(5):370-78.

Type 2 diabetes is a chronic condition that can lead to a great deal of individual suffering and economic loss. However, much of the morbidity associated with the long term microvascular and neuropathic complications can be avoided with tight glycemic control.

In early 2009, the American Diabetes Association (ADA) as well as the American Diabetes Association and the European Association for the Study of Diabetes (ADA/EASD) updated their consensus guidelines for treating type 2 diabetes. The consensus algorithm from the ADA/EASD has two treatment tiers; Tier 1 is "well-validated core therapies" which includes metformin + lifestyle as step 1, and metformin + lifestyle + basal insulin or a sulfonylurea as step 2, and metformin + lifestyle + intensive insulin as step 3. Tier 2 is considered "less well-validated therapies" and includes pioglitazone and GLP-1 agonists as alternatives. The guideline states that amylin agonists, α -glucosidase inhibitors, glinides, and DPP-4 inhibitors are not included in the two tiers of preferred agents in the treatment algorithm due to their lower or equivalent overall glucose-lowering effectiveness compared with the first and second-tier agents and/or to their limited clinical data. However, these agents may be appropriate in selected patients.^{1,2}

In addition, it is well established that self blood glucose monitoring in type 2 diabetics who are not using insulin is not cost effective. A trial published in the British Medical Journal in 2008 looked at the cost effectiveness of self monitoring of blood glucose in type 2 diabetics who were not using insulin. The data for this trial came from the randomized controlled diabetes glycemic education and monitoring (DiGEM) trial which looked at 12 months of data before the baseline and 12 months of trial follow up data. This study concluded that self monitoring of blood glucose with or without additional training in incorporating the results into self care was associated with higher costs and lower quality of life in patients with non-insulin treated type 2 diabetes.³ Similar results from different studies were recently published in the Canadian Medical Association Journal. The 2010 American Diabetes Association *Standards of Medical Care in Diabetes* states that the optimal frequency and timing of self blood glucose monitoring for patients with type 2 diabetes who are not using insulin is unclear.⁴

References:

1. Nathan DM, Buse JB, Davidson MB, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2009 Jan;32:193-203.
2. American Diabetes Association. Standards of medical care in diabetes—2009 [guideline on the Internet]. *Diabetes Care*. 2009 Jan [cited 2009 Dec 17];32 Suppl 1:S13-61.
3. Simon J, Gray A, Clarke P, Wade A, Neil A, Farmer A. Cost effectiveness of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. *BMJ (clinical research ed.)*; 2008 May 336 7654, 1177 (1177-80).
4. American Diabetes Association. Standards of medical care in diabetes – 2010 [guideline on the Internet]. *Diabetes care*. 2010. 2010 Jan [cited 2010 Jan 26]; 33 suppl 1:S11-61. Available from: http://care.diabetesjournals.org/content/33/Supplement_1/S11.full.pdf+html

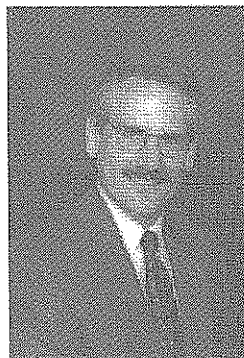
FDA Update

- Desipramine labeling has been updated with new safety information. The updated label states "extreme caution should be used when this drug is given to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances; and that seizures precede cardiac dysrhythmias and death in some patients." The label also warns that rates of death associate with desipramine overdose are higher than those of other tricyclic antidepressants.
- Due to reports of dispensing errors due to confusion with the drugs Casodex® (bicalutamine) and Kadian® (morphine sulfate), the FDA has approved the name change for the drug Kapidex™ (dexlansoprazole). Effective April 2010, Kapidex™ will be marketed under the new name Dexilant™.
- The FDA notified healthcare professionals regarding changes to the label for all diclofenac sodium containing products (including Voltaren gel®). New warnings and precautions are being added about the potential for elevation in liver function tests during treatment with diclofenac sodium. Cases of severe hepatic reactions, including liver necrosis, jaundice, hepatitis, and liver failure resulting in fatalities or liver transplantation have been reported. Transaminases should be monitored within 4 to 8 weeks after beginning treatment with diclofenac, based on postmarketing experiences and clinical trial data.
- The FDA issued a warning about a higher risk of myopathy in patients taking 80mg Zocor® (simvastatin) compared to patients taking lower doses of simvastatin—and possibly other statins.

Health Reform Legislation

- The President recently signed into law the Healthcare Reform bill which will allow for coverage expansion of uninsured persons beginning in 2014.
- Medicaid will be expanded to 133% of poverty level increasing Medicaid coverage by 16 million. Overall, the bill is expected to increase the number of Americans with insurance coverage to 92% of the population (95% excluding illegal immigrants) and increase the number of insured people by 32 million by 2019.
- The cost of Medicaid expansion will be fully funded by the federal government through 2016 at which time the federal matching rate will be decreased to 90% by 2020 for newly covered members.

Outgoing Member of the DUR Commission



Bruce Alexander, R.Ph., Pharm.D., has completed an eight year term of service with the Iowa Drug Utilization Review Commission. The Commission and the Department of Human Services wish to thank Dr. Alexander for his many years of service to the Commission and the members of Iowa Medicaid.

- The Commission finalized the Smoking Cessation report to the Department. A link to the report can be found on the Iowa Medicaid Drug Utilization Review website at iadur.org.
- The Commission mailed out the Quarterly Narcotic Utilization Report to Prescribers in February 2010. A total of 1,976 letters were mailed. DUR staff continues to receive phone calls from providers stating they do not have record of treating a listed member. The most common reason for this is incorrect information entered by the pharmacy. Prescribers need to contact the listed dispensing pharmacy to correct the information as Iowa Medicaid does not have the ability correct this. Prescribers also need to keep their information current with Iowa Medicaid by contacting Prescriber Services any time their information changes. Provider Services can be reached at 1-800-338-7909 or 515-256-4609.

Medicaid Statistics for Prescription Claims

from January 1, 2010 to March 31, 2010

Number of claims paid: 1,065,956

Average amount paid per claim: \$59.87

Total dollars paid: \$63,820,590.81

Average amount paid per claim, brand: \$204.78

Percent controlled substances: 18.59%

Average Amount paid per claim, generic: \$11.95

Top Drugs by Number of Prescriptions*	Top Drugs by Dollars Spent (Pre-Rebate)	Top Therapeutic Class by Dollars Spent (Pre-Rebate)
<i>ProAir HFA</i> \$43.76/RX	Synagis 100mg/ml \$1.8 million \$2,104.44/RX	Antipsychotics – Atypicals \$10.8 million
Hydrocodone/APAP 5-500 \$4.68/RX	Concerta 36mg \$980,930 \$194.74/RX	Stimulants – Amphetamines – Long Acting \$4.1 million
<i>Lexapro 20mg</i> \$87.14/RX	<i>Abilify 5mg</i> \$956,985 \$411.25/RX	Anticonvulsants \$3.8 million
Cheratussin AC \$5.96/RX	<i>Adderall XR 20mg</i> \$923,136 \$254.17/RX	Antidepressants – Selected SSRI's \$3.7 million

Appendix K

Web Site

Iowa Medicaid Drug Utilization Review Commission

- [DUR Information](#)
 - [Home](#)
- [Meeting Information](#)
 - [Agendas](#)
 - [Minutes](#)
 - [Newsletters](#)
 - [Members](#)
 - [Meeting Archive](#)
 - [Report Archive](#)
- [Mental Health Advisory Group](#)
- [Advisory Group Meeting Information](#)
 - [Advisory Group Minutes](#)
 - [Advisory Group Agendas](#)
 - [Contact](#)
- [DUR Commission](#)

Iowa Medicaid Drug Utilization Review Commission

New Public Comment Policy

Any data that are to be referenced during the Public Comment period(s) should be limited to published, peer reviewed literature only. "Data on file" and "articles submitted for review" are not considered published, peer reviewed literature and should not be referenced during public testimony. All referenced data that is to be presented should be submitted to the DUR professional staff electronically to info@iadur.org **AT LEAST ONE WEEK PRIOR TO THE MEETING DATE** for consideration and distribution to the Commission members.

Recent Site Updates

New [meeting information](#) has been added.

A new [DUR Digest](#) has been added.

DUR Commission Members

- Mark Graber, M.D., FACEP, Chairperson
- Laurie Pestel, Pharm.D., Vice Chairperson
 - Larry Ambrosion, R.Ph.
 - Casey Clor, M.D.
 - Brett Faine, Pharm.D.
- Craig Logemann, R.Ph., Pharm.D., BCPS
 - Susan Parker, Pharm.D.
 - Richard Rinehart, M.D.
- Sara Schutte-Schenck, D.O., FAAP

More information

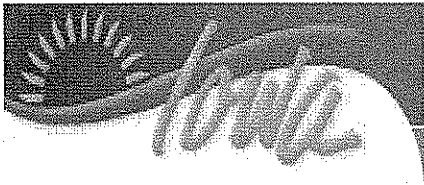
Professional Staff

- Thomas Kline, D.O. — Medical Director, Iowa Medicaid Enterprise
- Pam Smith, R.Ph. - DUR Project Coordinator

Visitor

Appendix L

Quarterly Management Reports



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 4	04/01/2009 through 06/30/2009
State Quarter 3	01/01/2009 through 03/31/2009

IOWA MEDICAID MANAGEMENT REPORT SUMMARY

COMPARISON OF QUARTERLY REPORTS

Average Amount Paid Per Claim:

State Fiscal Year:	\$63.58
State Quarter 4	\$63.88
State Quarter 3	\$65.71

Total Dollars Paid:

State Fiscal Year:	\$247,344,050.47
State Quarter 4	\$62,497,731.53
State Quarter 3	\$67,017,456.27

Number of Claims Paid:

State Fiscal Year:	3,890,294
State Quarter 4	978,425
State Quarter 3	1,019,834

Number of Eligible Members:

State Fiscal Year:	347,913
State Quarter 4	356,583
State Quarter 3	352,059

Number of Utilized Members:

State Fiscal Year:	293,760
State Quarter 4	182,901
State Quarter 3	192,288

Average Number of Claims per Utilized Member:

State Fiscal Year:	13.24
State Quarter 4	5.35
State Quarter 3	5.30

Percent Controlled Substances:

State Fiscal Year:	18.75%
State Quarter 4	18.82%
State Quarter 3	18.50%



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 4	04/01/2009 through 06/30/2009
State Quarter 3	01/01/2009 through 03/31/2009

Top Drugs per NDC by Number of Prescriptions

State Fiscal Year	State Quarter 4	State Quarter 3
1 PROAIR HFA AER	1 PROAIR HFA AER	1 PROAIR HFA AER
2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG
3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG
4 LORATADINE TAB 10MG	4 LORATADINE TAB 10MG	4 CHERATUSSIN SYP AC
5 CHERATUSSIN SYP AC	5 FERROUS SULF TAB 325MG	5 LORATADINE TAB 10MG

Drugs:

1 PROAIR HFA AER
2 HYDROCO/APAP TAB 5-500MG
3 LEXAPRO TAB 20MG
4 LORATADINE TAB 10MG
5 CHERATUSSIN SYP AC

Current Number of Claims

44,607
43,936
33,694
30,058
20,831

Top Drugs by Dollar Spent

State Fiscal Year	State Quarter 4	State Quarter 3
1 SYNAGIS INJ 100MG/ML	1 LEXAPRO TAB 20MG	1 SYNAGIS INJ 100MG/ML
2 ABILIFY TAB 10MG	2 ABILIFY TAB 5MG	2 ADDERALL XR CAP 20MG
3 ADDERALL XR CAP 20MG	3 ADDERALL XR CAP 20MG	3 LEXAPRO TAB 20MG
4 LEXAPRO TAB 20MG	4 ABILIFY TAB 10MG	4 ABILIFY TAB 10MG
5 ABILIFY TAB 5MG	5 CONCERTA TAB 36MG	5 ABILIFY TAB 5MG

Drugs:

1 SYNAGIS INJ 100MG/ML
2 ABILIFY TAB 10MG
3 ADDERALL XR CAP 20MG
4 LEXAPRO TAB 20MG
5 ABILIFY TAB 5MG

Total Paid:

\$5,089,149.33
\$3,119,661.27
\$3,018,810.43
\$2,896,627.12
\$2,864,285.24

State Fiscal Year: 07/01/2008 through 06/30/2009
 State Quarter 4 04/01/2009 through 06/30/2009
 State Quarter 3 01/01/2009 through 03/31/2009

Therapeutic Class by Total Prescription

State Fiscal Year	State Quarter 4	State Quarter 3
1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 BETA-LACTAMS / CLAVULANATE COMBO'S
3 NARCOTICS - MISC.	3 NARCOTICS - MISC.	3 ANTICONVULSANTS
4 ANXIOLYTICS - BENZODIAZEPINES	4 ANXIOLYTICS - BENZODIAZEPINES	4 NARCOTICS - MISC.
5 ANALGESICS - MISC.	5 ANALGESICS - MISC.	5 ANXIOLYTICS - BENZODIAZEPINES

Comparisons Trends:	State Quarter 4		State Quarter 3	
	Total Claims	Percent Total Claims	Total Claims	Percent Total Claims
ANTIDEPRESSANTS - SELECTED SSRI's	72,468	7.41	72,488	7.11
ANTICONVULSANTS	49,467	5.06	49,635	4.87
NARCOTICS - MISC.	48,418	4.95	47,959	4.70
ANXIOLYTICS - BENZODIAZEPINES	45,114	4.61	45,543	4.47
ANALGESICS - MISC.	39,831	4.07	41,645	4.08

Therapeutic Class by Dollars Spent

State Fiscal Year	State Quarter 4	State Quarter 3
1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 ANTICONVULSANTS
3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTIDEPRESSANTS - SELECTED SSRI's
4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 RSV PROPHYLAXIS
5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - AMPHETAMINES - LONG ACTING

Comparisons Trends:	State Quarter 4		State Quarter 3	
	Total Cost	Average Cost/Claim	Total Cost	Average Cost/Claim
ANTIPSYCHOTICS - ATYPICALS	\$10,970,535.07	\$291.50	\$12,152,658.36	\$319.84
ANTICONVULSANTS	\$5,549,690.45	\$112.19	\$5,625,631.85	\$113.34
ANTIDEPRESSANTS - SELECTED SSRI's	\$4,281,145.47	\$59.08	\$4,152,766.69	\$57.29
STIMULANTS - AMPHETAMINES - LONG ACTING	\$3,503,009.27	\$176.53	\$3,449,592.45	\$173.85
STIMULANTS - METHYLPHENIDATE - LONG ACTING	\$2,327,287.49	\$139.44	\$2,364,653.54	\$137.50



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 4	04/01/2009 through 06/30/2009
State Quarter 3	01/01/2009 through 03/31/2009

Generic Utilization:

BRAND MULTISOURCE

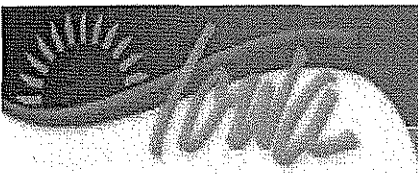
	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	7.31	\$158.62
State Quarter 4	5.88	\$173.59
State Quarter 3	7.38	\$160.72

BRAND SINGLESOURCE

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	23.94	\$180.19
State Quarter 4	23.68	\$187.65
State Quarter 3	23.28	\$192.92

GENERIC

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	68.75	\$12.87
State Quarter 4	70.43	\$13.08
State Quarter 3	69.34	\$12.90



State Fiscal Year:	07/01/2009 through 06/30/2010
State Quarter 1	07/01/2009 through 09/30/2009
State Quarter 4	04/01/2009 through 06/30/2009

IOWA MEDICAID MANAGEMENT REPORT SUMMARY

COMPARISON OF QUARTERLY REPORTS

Average Amount Paid Per Claim:

State Fiscal Year:	\$63.27
State Quarter 1	\$62.52
State Quarter 4	\$63.59

Total Dollars Paid:

State Fiscal Year:	\$246,721,793.94
State Quarter 1	\$62,854,354.45
State Quarter 4	\$62,550,119.67

Number of Claims Paid:

State Fiscal Year:	3,899,398
State Quarter 1	1,005,342
State Quarter 4	983,721

Number of Eligible Members:

State Fiscal Year:	349,430
State Quarter 1	366,476
State Quarter 4	361,153

Number of Utilized Members:

State Fiscal Year:	294,401
State Quarter 1	181,865
State Quarter 4	183,598

Average Number of Claims per Utilized Member:

State Fiscal Year:	13.25
State Quarter 1	5.53
State Quarter 4	5.36

Percent Controlled Substances:

State Fiscal Year:	18.76%
State Quarter 1	18.74%
State Quarter 4	18.84%



State Fiscal Year:	07/01/2009 through 06/30/2010
State Quarter 1	07/01/2009 through 09/30/2009
State Quarter 4	04/01/2009 through 06/30/2009

Top Drugs per NDC by Number of Prescriptions

State Fiscal Year	State Quarter 1	State Quarter 4
1 PROAIR HFA AER	1 PROAIR HFA AER	1 PROAIR HFA AER
2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG
3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG
4 LORATADINE TAB 10MG	4 LORATADINE TAB 10MG	4 LORATADINE TAB 10MG
5 FERROUS SULF TAB 325MG	5 FERROUS SULF TAB 325MG	5 FERROUS SULF TAB 325MG

Drugs:	Current Number of Claims
1 PROAIR HFA AER	44,609
2 HYDROCO/APAP TAB 5-500MG	43,962
3 LEXAPRO TAB 20MG	33,788
4 LORATADINE TAB 10MG	30,070
5 FERROUS SULF TAB 325MG	20,852

Top Drugs by Dollar Spent

State Fiscal Year	State Quarter 1	State Quarter 4
1 SYNAGIS INJ 100MG/ML	1 ABILIFY TAB 5MG	1 LEXAPRO TAB 20MG
2 ABILIFY TAB 10MG	2 ADDERALL XR CAP 20MG	2 ABILIFY TAB 5MG
3 ADDERALL XR CAP 20MG	3 LEXAPRO TAB 20MG	3 ADDERALL XR CAP 20MG
4 LEXAPRO TAB 20MG	4 CONCERTA TAB 36MG	4 ABILIFY TAB 10MG
5 ABILIFY TAB 5MG	5 ABILIFY TAB 10MG	5 CONCERTA TAB 36MG

Drugs:	Total Paid:
1 SYNAGIS INJ 100MG/ML	\$5,133,786.62
2 ABILIFY TAB 10MG	\$3,104,191.48
3 ADDERALL XR CAP 20MG	\$3,002,135.04
4 LEXAPRO TAB 20MG	\$2,889,097.95
5 ABILIFY TAB 5MG	\$2,845,774.78



State Fiscal Year: 07/01/2009 through 06/30/2010
 State Quarter 1 07/01/2009 through 09/30/2009
 State Quarter 4 04/01/2009 through 06/30/2009

Therapeutic Class by Total Prescription

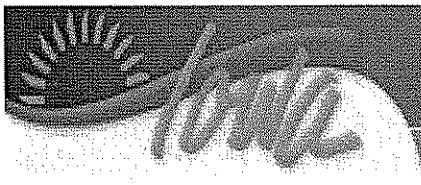
State Fiscal Year	State Quarter 1	State Quarter 4
1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 ANTICONVULSANTS
3 NARCOTICS - MISC.	3 NARCOTICS - MISC.	3 NARCOTICS - MISC.
4 ANXIOLYTICS - BENZODIAZEPINES	4 ANXIOLYTICS - BENZODIAZEPINES	4 ANXIOLYTICS - BENZODIAZEPINES
5 ANALGESICS - MISC.	5 ANALGESICS - MISC.	5 ANALGESICS - MISC.

Comparisons Trends:	State Quarter 1		State Quarter 4	
	Total Claims	Percent Total Claims	Total Claims	Percent Total Claims
ANTIDEPRESSANTS - SELECTED SSRI's	75,045	7.46	72,738	7.39
ANTICONVULSANTS	51,853	5.16	49,734	5.06
NARCOTICS - MISC.	50,127	4.99	48,702	4.95
ANXIOLYTICS - BENZODIAZEPINES	47,104	4.69	45,640	4.64
ANALGESICS - MISC.	41,422	4.12	40,948	4.16

Therapeutic Class by Dollars Spent

State Fiscal Year	State Quarter 1	State Quarter 4
1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 ANTICONVULSANTS
3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTIDEPRESSANTS - SELECTED SSRI's
4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 STIMULANTS - AMPHETAMINES - LONG ACTING
5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING

Comparisons Trends:	State Quarter 1		State Quarter 4	
	Total Cost	Average Cost/Claim	Total Cost	Average Cost/Claim
ANTIPSYCHOTICS - ATYPICALS	\$10,899,841.64	\$283.98	\$10,934,473.50	\$289.76
ANTICONVULSANTS	\$4,977,411.54	\$95.99	\$5,538,662.38	\$111.37
ANTIDEPRESSANTS - SELECTED SSRI's	\$4,382,847.77	\$58.40	\$4,276,753.45	\$58.80
STIMULANTS - AMPHETAMINES - LONG ACTING	\$3,774,038.87	\$187.24	\$3,485,527.54	\$175.62
STIMULANTS - METHYLPHENIDATE - LONG ACTING	\$2,373,828.12	\$143.44	\$2,307,997.12	\$138.23



State Fiscal Year:	07/01/2009 through 06/30/2010
State Quarter 1	07/01/2009 through 09/30/2009
State Quarter 4	04/01/2009 through 06/30/2009

Generic Utilization:

BRAND MULTISOURCE

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	7.42	\$158.32
State Quarter 1	4.90	\$167.21
State Quarter 4	5.99	\$173.10

BRAND SINGLESOURCE

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	23.88	\$178.89
State Quarter 1	24.25	\$184.81
State Quarter 4	23.60	\$186.69

GENERIC

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	68.70	\$12.81
State Quarter 1	70.85	\$13.43
State Quarter 4	70.41	\$13.01



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 2	10/01/2009 through 12/31/2009
State Quarter 1	07/01/2009 through 09/30/2009

IOWA MEDICAID MANAGEMENT REPORT SUMMARY

COMPARISON OF QUARTERLY REPORTS

Average Amount Paid Per Claim:

State Fiscal Year:	\$62.95
State Quarter 2	\$59.81
State Quarter 1	\$62.07

Total Dollars Paid:

State Fiscal Year:	\$245,584,522.00
State Quarter 2	\$64,236,696.20
State Quarter 1	\$62,725,712.40

Number of Claims Paid:

State Fiscal Year:	3,901,248
State Quarter 2	1,073,953
State Quarter 1	1,010,506

Number of Eligible Members:

State Fiscal Year:	349,801
State Quarter 2	373,114
State Quarter 1	370,204

Number of Utilized Members:

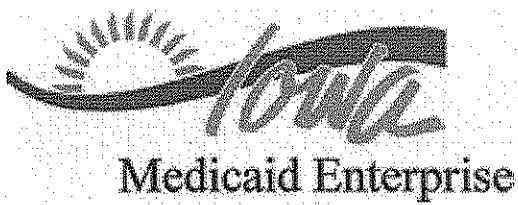
State Fiscal Year:	294,522
State Quarter 2	199,203
State Quarter 1	182,501

Average Number of Claims per Utilized Member:

State Fiscal Year:	13.25
State Quarter 2	5.39
State Quarter 1	5.54

Percent Controlled Substances:

State Fiscal Year:	18.76%
State Quarter 2	18.67%
State Quarter 1	18.77%



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 2	10/01/2009 through 12/31/2009
State Quarter 1	07/01/2009 through 09/30/2009

Top Drugs per NDC by Number of Prescriptions

State Fiscal Year	State Quarter 2	State Quarter 1
1 PROAIR HFA AER	1 PROAIR HFA AER	1 PROAIR HFA AER
2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG
3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG
4 LORATADINE TAB 10MG	4 CHERATUSSIN SYP AC	4 LORATADINE TAB 10MG
5 FERROUS SULF TAB 325MG	5 LORATADINE TAB 10MG	5 FERROUS SULF TAB 325MG

Drugs:

- 1 PROAIR HFA AER
- 2 HYDROCO/APAP TAB 5-500MG
- 3 LEXAPRO TAB 20MG
- 4 LORATADINE TAB 10MG
- 5 FERROUS SULF TAB 325MG

Current Number of Claims

44,623
43,962
33,804
30,068
20,862

Top Drugs by Dollar Spent

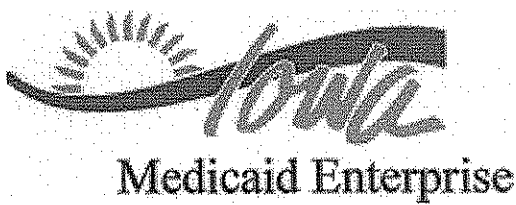
State Fiscal Year	State Quarter 2	State Quarter 1
1 SYNAGIS INJ 100MG/ML	1 SYNAGIS INJ 100MG/ML	1 ABILIFY TAB 5MG
2 ABILIFY TAB 10MG	2 CONCERTA TAB 36MG	2 ADDERALL XR CAP 20MG
3 ADDERALL XR CAP 20MG	3 ADDERALL XR CAP 20MG	3 LEXAPRO TAB 20MG
4 LEXAPRO TAB 20MG	4 ABILIFY TAB 5MG	4 CONCERTA TAB 36MG
5 ABILIFY TAB 5MG	5 LEXAPRO TAB 20MG	5 ABILIFY TAB 10MG

Drugs:

- 1 SYNAGIS INJ 100MG/ML
- 2 ABILIFY TAB 10MG
- 3 ADDERALL XR CAP 20MG
- 4 LEXAPRO TAB 20MG
- 5 ABILIFY TAB 5MG

Total Paid:

\$5,122,344.34
\$3,076,928.22
\$2,965,812.45
\$2,877,870.92
\$2,820,024.16



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 2	10/01/2009 through 12/31/2009
State Quarter 1	07/01/2009 through 09/30/2009

Therapeutic Class by Total Prescription

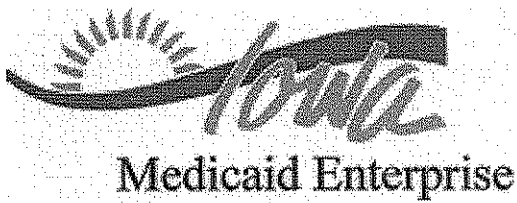
State Fiscal Year	State Quarter 2	State Quarter 1
1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 ANTICONVULSANTS
3 NARCOTICS - MISC.	3 NARCOTICS - MISC.	3 NARCOTICS - MISC.
4 ANXIOLYTICS - BENZODIAZEPINES	4 ANXIOLYTICS - BENZODIAZEPINES	4 ANXIOLYTICS - BENZODIAZEPINES
5 ANALGESICS - MISC.	5 BETA-LACTAMS / CLAVULANATE COMBO'S	5 ANALGESICS - MISC.

Comparisons Trends:	State Quarter 2		State Quarter 1	
	Total Claims	Percent Total Claims	Total Claims	Percent Total Claims
ANTIDEPRESSANTS - SELECTED SSRI's	76,516	7.12	75,310	7.45
ANTICONVULSANTS	52,124	4.85	52,196	5.17
NARCOTICS - MISC.	49,417	4.60	50,415	4.99
ANXIOLYTICS - BENZODIAZEPINES	47,172	4.39	47,647	4.72
BETA-LACTAMS / CLAVULANATE COMBO'S	43,732	4.07	30,371	3.01

Therapeutic Class by Dollars Spent

State Fiscal Year	State Quarter 2	State Quarter 1
1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 ANTICONVULSANTS
3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTIDEPRESSANTS - SELECTED SSRI's
4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 STIMULANTS - AMPHETAMINES - LONG ACTING
5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING

Comparisons Trends:	State Quarter 2		State Quarter 1	
	Total Cost	Average Cost/Claim	Total Cost	Average Cost/Claim
ANTIPSYCHOTICS - ATYPICALS	\$10,639,996.16	\$270.72	\$10,842,887.97	\$281.48
ANTICONVULSANTS	\$4,282,967.53	\$82.17	\$4,956,942.86	\$94.97
ANTIDEPRESSANTS - SELECTED SSRI's	\$4,213,272.02	\$55.06	\$4,384,844.46	\$58.22
STIMULANTS - AMPHETAMINES - LONG ACTING	\$3,908,763.83	\$178.45	\$3,732,824.88	\$185.08
STIMULANTS - METHYLPHENIDATE - LONG ACTING	\$2,559,475.81	\$144.33	\$2,350,576.34	\$141.92



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 2	10/01/2009 through 12/31/2009
State Quarter 1	07/01/2009 through 09/30/2009

Generic Utilization:

BRAND MULTISOURCE

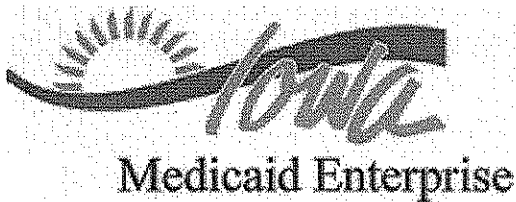
	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	7.95	\$160.45
State Quarter 2	5.02	\$162.89
State Quarter 1	5.63	\$172.27

BRAND SINGLESOURCE

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	23.34	\$177.46
State Quarter 2	22.87	\$184.52
State Quarter 1	23.39	\$183.24

GENERIC

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	68.71	\$12.77
State Quarter 2	72.11	\$13.09
State Quarter 1	70.98	\$13.40



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 3	01/01/2010 through 03/31/2010
State Quarter 2	10/01/2009 through 12/31/2009

IOWA MEDICAID MANAGEMENT REPORT SUMMARY

COMPARISON OF QUARTERLY REPORTS

Average Amount Paid Per Claim:

State Fiscal Year:	\$62.52
State Quarter 3	\$59.87
State Quarter 2	\$58.80

Total Dollars Paid:

State Fiscal Year:	\$244,003,260.58
State Quarter 3	\$63,820,590.81
State Quarter 2	\$63,513,575.55

Number of Claims Paid:

State Fiscal Year:	3,902,910
State Quarter 3	1,065,956
State Quarter 2	1,080,196

Number of Eligible Members:

State Fiscal Year:	350,002
State Quarter 3	379,425
State Quarter 2	377,370

Number of Utilized Members:

State Fiscal Year:	294,632
State Quarter 3	199,572
State Quarter 2	199,852

Average Number of Claims per Utilized Member:

State Fiscal Year:	13.25
State Quarter 3	5.34
State Quarter 2	5.40

Percent Controlled Substances:

State Fiscal Year:	18.76%
State Quarter 3	18.59%
State Quarter 2	18.70%



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 3	01/01/2010 through 03/31/2010
State Quarter 2	10/01/2009 through 12/31/2009

Top Drugs per NDC by Number of Prescriptions

State Fiscal Year	State Quarter 3	State Quarter 2
1 PROAIR HFA AER	1 PROAIR HFA AER	1 PROAIR HFA AER
2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG	2 HYDROCO/APAP TAB 5-500MG
3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG	3 LEXAPRO TAB 20MG
4 LORATADINE TAB 10MG	4 CHERATUSSIN SYP AC	4 CHERATUSSIN SYP AC
5 FERROUS SULF TAB 325MG	5 ALBUTEROL NEB 0.083%	5 LORATADINE TAB 10MG

Drugs:

- 1 PROAIR HFA AER
- 2 HYDROCO/APAP TAB 5-500MG
- 3 LEXAPRO TAB 20MG
- 4 LORATADINE TAB 10MG
- 5 FERROUS SULF TAB 325MG

Current Number of Claims

- 44,641
- 43,971
- 33,840
- 30,074
- 20,869

Top Drugs by Dollar Spent

State Fiscal Year	State Quarter 3	State Quarter 2
1 SYNAGIS INJ 100MG/ML	1 SYNAGIS INJ 100MG/ML	1 SYNAGIS INJ 100MG/ML
2 ABILIFY TAB 10MG	2 CONCERTA TAB 36MG	2 CONCERTA TAB 36MG
3 ADDERALL XR CAP 20MG	3 ABILIFY TAB 5MG	3 ADDERALL XR CAP 20MG
4 LEXAPRO TAB 20MG	4 ADDERALL XR CAP 20MG	4 ABILIFY TAB 5MG
5 ABILIFY TAB 5MG	5 LEXAPRO TAB 20MG	5 LEXAPRO TAB 20MG

Drugs:

- 1 SYNAGIS INJ 100MG/ML
- 2 ABILIFY TAB 10MG
- 3 ADDERALL XR CAP 20MG
- 4 LEXAPRO TAB 20MG
- 5 ABILIFY TAB 5MG

Total Paid:

- \$5,119,146.43
- \$3,040,144.24
- \$2,912,262.63
- \$2,859,994.06
- \$2,779,691.95

Therapeutic Class by Total Prescription

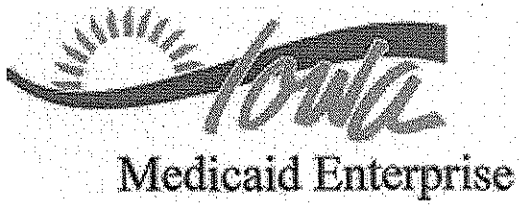
State Fiscal Year	State Quarter 3	State Quarter 2
1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's	1 ANTIDEPRESSANTS - SELECTED SSRI's
2 ANTICONVULSANTS	2 ANTICONVULSANTS	2 ANTICONVULSANTS
3 NARCOTICS - MISC.	3 NARCOTICS - MISC.	3 NARCOTICS - MISC.
4 ANXIOLYTICS - BENZODIAZEPINES	4 BETA-LACTAMS / CLAVULANATE COMBO'S	4 ANXIOLYTICS - BENZODIAZEPINES
5 ANALGESICS - MISC.	5 ANXIOLYTICS - BENZODIAZEPINES	5 BETA-LACTAMS / CLAVULANATE COMBO'S

Comparisons Trends:	State Quarter 3		State Quarter 2	
	Total Claims	Percent Total Claims	Total Claims	Percent Total Claims
ANTIDEPRESSANTS - SELECTED SSRI's	77,539	7.27	76,934	7.12
ANTICONVULSANTS	52,463	4.92	52,551	4.86
NARCOTICS - MISC.	49,699	4.66	49,697	4.60
BETA-LACTAMS / CLAVULANATE COMBO'S	47,579	4.46	43,752	4.05
ANXIOLYTICS - BENZODIAZEPINES	47,096	4.42	47,876	4.43

Therapeutic Class by Dollars Spent

State Fiscal Year	State Quarter 3	State Quarter 2
1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS	1 ANTIPSYCHOTICS - ATYPICALS
2 ANTICONVULSANTS	2 STIMULANTS - AMPHETAMINES - LONG ACTING	2 ANTICONVULSANTS
3 ANTIDEPRESSANTS - SELECTED SSRI's	3 ANTICONVULSANTS	3 ANTIDEPRESSANTS - SELECTED SSRI's
4 STIMULANTS - AMPHETAMINES - LONG ACTING	4 ANTIDEPRESSANTS - SELECTED SSRI's	4 STIMULANTS - AMPHETAMINES - LONG ACTING
5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING	5 STIMULANTS - METHYLPHENIDATE - LONG ACTING

Comparisons Trends:	State Quarter 3		State Quarter 2	
	Total Cost	Average Cost/Claim	Total Cost	Average Cost/Claim
ANTIPSYCHOTICS - ATYPICALS	\$10,868,145.21	\$278.11	\$10,449,947.50	\$264.21
STIMULANTS - AMPHETAMINES - LONG ACTING	\$4,118,628.70	\$180.52	\$3,783,924.41	\$172.46
ANTICONVULSANTS	\$3,850,908.38	\$73.40	\$4,225,227.20	\$80.40
ANTIDEPRESSANTS - SELECTED SSRI's	\$3,716,560.51	\$47.93	\$4,202,283.85	\$54.62
STIMULANTS - METHYLPHENIDATE - LONG ACTING	\$2,701,158.35	\$149.24	\$2,474,159.49	\$139.44



State Fiscal Year:	07/01/2008 through 06/30/2009
State Quarter 3	01/01/2010 through 03/31/2010
State Quarter 2	10/01/2009 through 12/31/2009

Generic Utilization:

BRAND MULTISOURCE

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	7.99	\$158.48
State Quarter 3	3.93	\$167.99
State Quarter 2	5.06	\$159.53

BRAND SINGLESOURCE

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	23.31	\$176.42
State Quarter 3	21.67	\$204.78
State Quarter 2	22.76	\$181.92

GENERIC

	Percent of Claims	Average Amount Paid per Claim
State Fiscal Year	68.70	\$12.71
State Quarter 3	74.40	\$11.95
State Quarter 2	72.18	\$12.91

Appendix M

Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes August 5, 2009

Attendees:

Commission Members
Rick Rinehart, M.D.; Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Casey Clor, M.D.; Mark Graber, M.D., FACEP; and Susan Parker, Pharm.D.
Staff
Thomas Kline, D.O.; Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.
Guests
Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Thomas Kline called the meeting to order at 9:33 a.m. at the Hoover Building in Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the June 3, 2009 meeting were approved following some noted corrections. (Motion by Bruce Alexander, second by Dr. Rick Rinehart, unanimous approval by voice vote.)

The Commission members were reminded they needed to complete their annual Conflict of Interest Disclosure forms, Business Associates' Agreement, and Confidentiality forms. They also elected Dr. Mark Graber as Chairperson (Bruce Alexander nominated him, and Craig Logemann seconded) and Laurie Pestel as Vice-Chairperson (Dr. Rick Rinehart nominated her, and Bruce Alexander seconded).

The Commission developed a new policy for literature cited during public comment. Any data that are to be referenced during the Public Comment period(s) should be limited to published, peer reviewed literature only. "Data on file" and "articles submitted for review" are not considered published, peer reviewed literature and should not be referenced during public testimony. All referenced data that is to be presented should be submitted to the DUR professional staff electronically at info@iadur.org at least one week prior to the meeting date for consideration and distribution to the Commission members. This policy applies to any articles Commission members bring to the meetings themselves, as well. Craig Logemann motioned to accept this new policy, and Bruce Alexander seconded. The motion passed with no objections.

Iowa Medicaid Enterprise Updates

The Medical Services department at the IME is attempting to obtain URAC accreditation. As part of this process, all of Medical Services' policies are up for review at the next Clinical Advisory Committee meeting. There is a current state-wide movement to develop a patient-centered medical home. The University of Iowa is sponsoring this project, and there will be a meeting September 18th to discuss it. The SSDC met in June to discuss supplemental rebate negotiation. The P&T Committee will have its annual review of the PDL in November. Any changes will be effective January 1, 2010. The Department of Human Services has put out a letter stating they will be providing RFP in the fall of this year for 7 of the 9 contracts that are currently being handled at the IME. New contracts will be effective July 1, 2010. Chad Bissell explained how his new position with the company contracted to provide the professional staffing services for the DUR Commission has resulted in a transition of primary duties to Pam Smith.

Management Reports for Quarter 4

Iowa Medicaid member enrollment, as well as number of claims, was down in the 4th Quarter of State Fiscal Year 2009 compared to Quarter 3. The average price per claim was \$63.88, which was also less than the \$65.71 average for the 3rd quarter. Generic utilization is over 70% now. Behavioral Health drugs continue to dominate the top 5 drugs by dollars spent and top therapeutic classes by total prescriptions reports. However, Synagis was the top drug by dollars spent for the entire fiscal year, and ProAir HFA had the most prescriptions for SFY 2009.

Public Comment

Lisa Goetz, Pharm.D. (MedImmune) and Susan Harrell, M.D. both spoke about Synagis. Geoff Wall, Pharm.D., from Iowa Methodist Medical Center spoke about Uloric.

PA Criteria

Thrombopoietin Receptor Agonists: The Commission reviewed the prior authorization criteria as follows:

Payment for a preferred thrombopoietin receptor agonist will only be considered for cases in which there is a diagnosis of chronic immune thrombocytopenic purpura (ITP) in addition to documentation of a recent trial and therapy failure with a preferred corticosteroid, a preferred immunoglobulin, and/or the member has undergone a splenectomy. Payment for a non-preferred thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred thrombopoietin receptor agonist unless such a trial would be medically contraindicated.

The Commission members had no further comments regarding these criteria. This recommendation will be sent to the Department for consideration.

Uloric: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for febuxostat (Uloric). Payment for febuxostat (Uloric) will only be considered for cases in which symptoms of gout still persist while currently using a therapeutic dose of 300mg per day on a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

Bruce Alexander motioned to accept, Dr. Mark Graber seconded, and the motion passed unanimously. Craig Logemann also motioned that a quantity limit be placed on the 40mg Uloric tablet, limiting to 30 for 30 days, since the 40mg and 80mg tablets are the same price. Larry Ambrosion seconded this. This also passed with no objections; however, Bruce Alexander abstained, as he was out of the room during the end of the discussion. Additionally, Pam Smith and Susan Parker explained how FUL and SMAC pricing, OBRA, and supplemental rebates work for the new Commission members. These recommendations will be sent to the medical and pharmacy association(s) for comments.

Palivizumab (Synagis): In June, 2009, Red Book modified their guidelines for use of palivizumab (Synagis) for RSV prevention in high-risk infants and young children. Using additional data regarding the seasonality of RSV and risk factors for babies born between 32 and 35 weeks gestation, the guidelines for use have been modified to ensure cost/benefit optimization. The updated recommendations include:

1. *Modification of recommendations for initiation and termination of RSV prophylaxis based on current CDC descriptions of seasonality in different areas of the United States.*
2. *Emphasis on need for no more than a maximum of 5 doses in all geographic areas.*
3. *Modification of risk factors for severe disease (congenital abnormalities of the airway or neuromuscular disease) in infants less than 12 months of age and born before 35 weeks of gestation.*
4. *For infants 32 through 35 weeks of gestation who qualify for prophylaxis based on presence of risk factors, prophylaxis is recommended beyond 90 days of age (maximum of 3 doses)*

The Commission decided to leave the Iowa Medicaid criteria for Synagis the same as what was used last year for now due to the lack of published evidence behind the new Red Book guidelines. The start date for PAs will be November 1st (unless virology data shows it should be earlier), with an initial 5 doses approved; additional doses would be contingent upon RSV epidemiology data collected by the Iowa Department of Public Health. However, this decision may be re-evaluated once the data that spawned the new Red Book guidelines is released.

Annual Review of Clinical PA Criteria: The Commission members suggested some changes to existing PA criteria. Pam Smith recommended that since OTC cetirizine is now available (and a much more cost-effective alternative), that the criteria on the Antihistamine PA form be modified to require 3 preferred trials

(among them OTC cetirizine and OTC loratadine) for any member 20 years of age or older, and a trial of both OTC cetirizine and OTC loratadine for anyone younger than 20. In the Biologicals for Ankylosing Spondylitis category, Chad Bissell recommended requiring a trial of 2 NSAIDs for a duration of 3 months, which matches the requirements of the Spartan Guidelines. If a member had only peripheral symptoms, they would also have to have a trial of a preferred DMARD product, such as sulfasalazine or methotrexate. For the Biologicals for Rheumatoid Arthritis, Dr. Graber made a comment about updated guidelines suggesting two DMARDS be tried prior to initiation therapy with a biological. These guidelines will be reviewed more closely and brought to a future meeting. It was suggested that the Ergotamine Derivatives PA form no longer be required as the category is not being utilized. A new product will be added to the Fentanyl PA Form. There will be new wording on the Ketorolac PA Form, as there is no longer a preferred ketorolac agent, as follows: "*prior to the consideration of IM/IV Ketorolac Injection, a recent trial and therapy failure with two preferred COX-2 preferentially selective NSAIDs*". In the Muscle Relaxants category, Pam Smith said long term use of the non-preferred agents, specifically carisoprodol, had been an issue within the PA Department. Recommended duration of therapy with this drug is two to three weeks, and requests for chronic treatment are not uncommon. Susan Parker asked that Wellbutrin and Zyban be added to the Nicotine Replacement PA Form. Pam Smith said that the Pregabalin PA Form needed to be more specific; "at adequate doses" should be added to all line items so they match. Sandy Pranger suggested that criteria needed to be developed for Lidoderm, as Iowa sported the highest utilization at the SSDC meeting. Also, Januvia was suggested to have criteria developed. These criterion will be brought to future meetings for more specific discussion.

Public Comment

There were no speakers in this public comment section.

Focus Studies

Duplicate SSRIs: The purpose of this study was to follow-up on the 15 unique members identified as having duplicate SSRIs in their claims history for three consecutive months during the time frame 8/1/08 to 10/31/08. Letters were sent to providers at the end of December, 2008. Five unique members were still using duplicate SSRI therapy after DUR intervention. Ten members discontinued duplicate therapy which resulted in a total savings of \$8,723.49 (State and Federal, pre-rebate), of which \$3,280.03 (pre-rebate) were State funds.

Long Acting Narcotics Plus Methadone: The purpose of this study was to follow-up on the 16 unique members identified as using methadone in combination with other long acting narcotics in their claims history during the time frame 8/1/08 to 11/30/08. Letters were sent to providers at the end of November, 2008. Ten unique members were still using methadone in combination with long acting narcotics after DUR intervention. However, six members' therapy changes resulted in a total savings of \$2,081.70 (State and Federal, pre-rebate), of which \$782.72 (pre-rebate) were State funds.

Benzodiazepines without SSRI/SNRI: The purpose of this study was to determine how many Iowa Medicaid members are being treated for various anxiety disorders with benzodiazepines but not a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI). At the February 2009 DUR Meeting, a report was generated which looked at duplicate benzodiazepine utilization for members between the time period of 9/1/2008 through 11/30/2008. This report found 300 unique members who were using two or more benzodiazepines concurrently. In the discussion, an interest was expressed to look at members who were being treated for anxiety disorders with benzodiazepines but not an SSRI/SNRI. A second report was reviewed at the June 2009 DUR meeting which looked at benzodiazepine use without an SSRI/SNRI. Following a review of the diagnosis codes used to develop the study population, some changes were recommended. This report was run looking at members with a diagnosis code of panic disorder with agoraphobia, panic disorder without agoraphobia, obsessive-compulsive disorder, and/or dysthymic disorder at anytime in their medical claims history. Members with Medicare Part D eligibility were excluded from this analysis. These members' pharmacy claim histories were reviewed to identify utilization with SSRI/SNRIs and benzodiazepines between the dates of 6/1/2008 and 6/30/2009. Those members who had two or more months of utilization with SSRI/SNRIs and benzodiazepines that continued therapy through the month of June, 2009 are reported. Eight thousand, seven hundred sixty members were identified as fitting these diagnostic criteria. As of June 2009, 45 members were still using BZD but no SSRI/SNRI, 578 members were using both SSRI/SNRI and BZD concurrently, and 912 members were using SSRI/SNRI but no BZD. With such a small number of members, the Commission decided not to send letters. However, they asked that the data be re-run to evaluate if the members fitting the criteria but not taking BZD or SSRI/SNRIs were on Antipsychotics or Tricyclics. These findings will be brought to the November meeting.

Utilization of Products for Influenza: The purpose of this study was to provide trending information over several recent years' influenza treatment and outpatient vaccine utilization within the Iowa Medicaid population. (These data were collected prior to when the 2009 H1N1 influenza strain was identified.) Influenza is a highly contagious upper respiratory tract infection that affects several million Americans each year. Drugs that are commonly used to treat or prevent influenza, oseltamivir (Tamiflu), zanamivir (Relenza), amantadine, rimantadine, and the annual influenza vaccine, all appear on the Preferred Drug List as preferred products. During the 2008-2009 influenza season, the Centers for Disease Control (CDC) and Prevention revised their recommendations for treating seasonal influenza a couple of months into the influenza season after a high percentage of isolated strains showed resistance to oseltamivir (Tamiflu) and zanamivir (Relenza). The utilization data suggests that providers followed the CDC's revised recommendations when treating members with influenza. There is currently a quantity limit in place for oseltamivir (Tamiflu) for quantities greater than 75mL for the liquid and 14 units for the capsules. Compared to other Sovereign State Drug Consortium states, Iowa has extremely high utilization of

oseltamivir (Tamiflu) compared to other states of similar Medicaid size. Additionally, prior to the 2008-2009 season, there were several cases where members were treated twice in the same season with oseltamivir (Tamiflu). Susan Parker suggested contacting Iowa Medicaid Member Services to see if they had any informational letters planned for this topic.

Chronic Use of Metoclopramide: The purpose of this study was to identify instances where Iowa Medicaid members are using metoclopramide on a chronic basis or high doses in light of the new black box warning issued by the FDA. Metoclopramide stimulates the upper gastrointestinal tract to increase motility and increase the rate of stomach emptying. It is FDA approved for short-term management of gastroesophageal reflux disease (GERD), diabetic gastroparesis, and nausea. Short-term management is defined as 4 to 12 weeks by the manufacturers of metoclopramide. Recently, the FDA announced that manufacturers of metoclopramide must include a Black Box Warning regarding the risk of developing tardive dyskinesia after receiving reports of this side effect with long term use or use at high doses. The symptoms of tardive dyskinesia are often times irreversible, and may continue to be bothersome for a considerable time following the discontinuation of the causative agent. The FDA reports suggest that metoclopramide is the most common cause of drug-induced tardive dyskinesia. A claims analysis was conducted over a six month time frame (1/1/09 through 6/30/09) to identify: 1) unique members (adult and children) with one or more fills of metoclopramide in their claims history, and 2) the number of unique members using a high dose of metoclopramide (>60mg/day) for more than two months. Due to a higher rate of extrapyramidal side effects, the manufacturer does not recommend the use of metoclopramide in children. However, metoclopramide has been known to be used off-label in children for GERD. A second analysis was done to determine the extent of chronic metoclopramide use at three and four or more consecutive months. There were 23 members taking metoclopramide for four or more consecutive months, and four unique members on a high dose (more than 60mg per day). Dr. Wadle suggested that direct contact would achieve better results with this small population than an article in the DUR Digest. Some further analyses will be done to determine how many providers are involved in prescribing metoclopramide for long term use or at high doses.

Miscellaneous

SMAC Update: The Commission members were given a copy of the SMAC changes effective August 14, 2009.

FUL Update: The Commission members were given a copy of the CMS FUL changes that were implemented July 17, 2009.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 12:26 to adjourn the meeting and move to closed

session (1st by Bruce Alexander 2nd by Dr. Rick Rinehart).

The next meeting will be held at 9:30 a.m. on Wednesday, September 2, 2009 at the Learning Resource Center in West Des Moines, IA.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes September 2, 2009

Attendees:

Commission Members

Rick Rinehart, M.D.; Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambrosion, R.Ph.; Casey Clor, M.D.; Mark Graber, M.D., FACEP; and Susan Parker, Pharm.D.

Staff

Thomas Kline, D.O.; Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Thomas Kline called the meeting to order at 9:30 a.m. at the Learning Resource Center in West Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the August 5, 2009 meeting were approved following a correction from Bruce Alexander. (Motion by Dr. Rick Rinehart, second by Dr. Sara Schutte-Schenck, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

Medical Services has been investigating prior authorization of elective CTs, MRIs, PET scans, and MRAs for possible future savings. An estimated \$27 million was spent on these last year, so there is an opportunity for savings. Medical Services is also in the process of developing a maternal health program with the Department of Public Health, attempting to identify all high-risk pregnant women in the state in their first trimester. Medical Services is working toward URAC accreditation. There will be a Clinical Advisory Committee meeting on September 11th; they will discuss Medipass provider reporting among other topics. The Mental Health Advisory Group meeting scheduled for Friday October 23rd has now been cancelled.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these three examples resulted in an annualized total savings of \$16,871.65 pre-rebate (state and federal).

Public Comment

Patricia Harwood (MedImmune) and Susan Harrell (Blank Children's Hospital) both spoke about *Synagis*. Nancy Bell from Pfizer spoke about changes to the

Lyrica prior authorization criteria.

PA Criteria

Uloric: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for febuxostat (Uloric). Payment for febuxostat (Uloric) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

There were four responses from members of the Iowa Pharmacy Association, in response to letters that had been sent out regarding these proposed criteria. Commission members were given a copy, but had no further changes. Bruce Alexander did suggest that the informational letter include an explanation of why the uric acid level was not part of the criteria as it had come up in discussion.

Ketorolac: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ketorolac tromethamine, a nonsteroidal anti-inflammatory drug indicated for short term (up to five days) management of moderately severe, acute pain. It is NOT indicated for minor or chronic conditions. This product carries a Black Box Warning. Initiate therapy with IV/IM and use oral ketorolac tromethamine only as a continuation therapy to ketorolac tromethamine IV/IM. The combined duration of use of IV/IM and oral is not to exceed five (5) days. Payment will be approved under the following conditions:

- 1. For oral therapy, documentation of recent IM/IV ketorolac tromethamine injection including administration date and time, and the total number of injections given.*
 - 2. Request falls within the manufacturer's dosing guidelines. Maximum oral dose is 40mg/day. Maximum IV/IM dose is 120mg/day. Maximum duration of therapy is 5 days per month.*
 - 3. Diagnosis indicating moderately severe, acute pain.*
- Requests for IV/IM ketorolac must document previous trials and therapy failures with at least two preferred nonsteroidal anti-inflammatory drugs.*

The Commission asked that language be added to the last sentence indicating the two nonsteroidal anti-inflammatory drug trials be at an adequate dose to keep consistent with other PA criteria. Bruce Alexander motioned to accept these criteria with the suggested change, and Craig Logemann seconded. The motion passed with no objections.

Muscle Relaxants: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred muscle relaxants. Payment for non-preferred muscle relaxants will be authorized only for cases in which there is documentation of previous trials and therapy failures with at least three preferred

muscle relaxants. Requests for carisoprodol will be approved for a maximum of 120 tablets per 30 days within a six month timeframe when the criteria for coverage are met.

Dr. Rick Rinehart motioned to accept these criteria, and Larry Ambrosion seconded. The motion passed unanimously.

Antihistamines: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred antihistamines and preferred 2nd generation prescription antihistamines.

Patients 21 years of age and older must have three unsuccessful trials with antihistamines that do not require prior authorization, prior to the approval of a preferred 1st generation or preferred 2nd generation prescription antihistamine. Two of the trials must be otc cetirizine and loratadine. Prior to approval of a non-preferred 2nd generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred 2nd generation prescription antihistamine.

Patients 20 years of age and younger must have unsuccessful trials with otc cetirizine and loratadine prior to the approval of a non-preferred 1st generation or preferred 2nd generation prescription antihistamine. Prior to approval of a non-preferred 2nd generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred 2nd generation prescription antihistamine.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Craig Logemann motioned to accept these criteria, and Bruce Alexander seconded. The motion passed unanimously.

Fentanyl – Short Acting Oral Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for short acting oral fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients. These products carry a Black Box Warning. Actiq®, Fentora®, & Onsolis™:

- Are indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain.*

Are contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, do not use in opioid non-tolerant patients.

Bruce Alexander motioned to accept these criteria, and Dr. Rick Rinehart seconded. The motion passed unanimously.

Pregabalin (Lyrica): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for pregabalin (Lyrica®). Payment will be considered under the following conditions:

- 1. A diagnosis of partial onset seizures, as adjunct therapy.*
- 2. A diagnosis of post-herpetic neuralgia and previous treatment failure with at least two of the following agents at a therapeutic dose to treat post-herpetic neuralgia: tricyclic antidepressant, topical lidocaine, or gabapentin.*
- 3. A diagnosis of diabetic peripheral neuropathy and previous treatment failure with at least two of the following agents at a therapeutic dose to treat diabetic peripheral neuropathy: tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin.*
- 4. A diagnosis of fibromyalgia and a previous treatment failure with a preferred agent at a therapeutic dose to treat fibromyalgia.*

This topic was deferred to a future meeting so as to give time to review why the original language did not have “a therapeutic dose” added to #2 and #3. Bruce Alexander motioned that all references to “adequate” dose on all PA forms be replaced with “therapeutic” dose. Dr. Mark Graber seconded, and the motion passed with no objections.

Palivizumab (Synagis): In August 2009, the American Academy of Pediatrics modified their guidelines for use of palivizumab (Synagis) for RSV prevention in high-risk infants and young children. Using additional data regarding the seasonality of RSV and risk factors for babies born between 32 and 35 weeks gestation, the guidelines for use have been modified to ensure cost/benefit optimization. The updated recommendations include:

- 1. Modification of recommendations for initiation and termination of RSV prophylaxis based on current CDC descriptions of seasonality in different areas of the United States.*
- 2. Emphasis on need for no more than a maximum of 5 doses in all geographic areas.*
- 3. Modification of risk factors for severe disease (congenital abnormalities of the airway or neuromuscular disease) in infants less than 12 months of age and born before 35 weeks of gestation.*
- 4. For infants 32 through 35 weeks of gestation who qualify for prophylaxis based on presence of risk factors, prophylaxis is recommended beyond 90 days of age (maximum of 3 doses)*

Dr. Mark Graber motioned to move the start date for Synagis coverage back to November 16th and to allow for 5 doses, which would bring some cost savings for the State. Dr. Casey Clor seconded, and the motion passed unanimously. As the Commission then seemed to be at a standstill regarding their opinion of adopting the new Red Book guidelines, Dr. Mark Graber motioned to accept the Red Book guidelines/AAP policy statement and Dr. Casey Clor seconded.

However, upon voting, the majority opposed this motion, as well as 3 (Laurie Pestel, Dr. Mark Graber, and Dr. Sarah Schutte-Schenck) abstaining. Therefore, the *Synagis* PA criteria will remain the same as last year, but with the modified start date and maximum of 5 doses for the season.

Public Comment

There were no speakers in this public comment section.

Focus Studies

Tiotropium plus Ipratropium: The purpose of this study was to follow-up on the 35 unique members identified as having duplicate inhaled anticholinergics (tiotropium and ipratropium) in their claims history between the time period of 9/1/2008 through 11/30/2008. Letters were sent to providers in March, 2009. Following the intervention, there were only 17 members using duplicate therapy, a change which brought about a cost savings of \$60,629.33 (state and federal pre-rebate).

ACE Inhibitors combined with Angiotensin Receptor Blockers: The purpose of this study was to identify instances where Iowa Medicaid members are using Angiotensin Converting Enzyme (ACE) Inhibitors in combination with Angiotensin Receptor Blockers (ARB). The ONgoing Tehnisartan Alone, in combination with Ramipril Global Endpoint Trial (ONTARGET) was a multi-year study that examined 25,620 patients to compare the effects of telmisartan (*Micardis*) alone, telmisartan in combination with ramipril (*Altace*), and an ACE Inhibitor alone in patients with established atherosclerotic vascular disease or diabetes with end-organ damage who were 55 years of age or older. Patients who used the ACE Inhibitor and ARB combination had 2-3 mm/Hg lower overall blood pressure compared to patients using monotherapy; however, more patients experienced hypotensive side effects when using the combination. Overall, the primary outcome (death from cardiovascular causes, myocardial infarction, stroke, hospitalization for heart failure, time to first dialysis, doubling of serum creatinine, or death) was the same in all three groups of patients. Therefore, the combination of ACE Inhibitors and ARBs is not recommended as it does not reduce poor outcomes and actually increases the likelihood of adverse drug events compared to either drug used alone. However, these findings do not apply to patients with congestive heart failure, as this group of patients was specifically excluded from the ONTARGET trial. Potential benefits of combining ACE Inhibitors and ARBs have been found in studies of patients with poorly controlled congestive heart failure. Reports also show that the combination of an ACE Inhibitor and an ARB is superior to either therapy alone in decreasing proteinuria in patients with diabetic nephropathy. An analysis was performed looking at three months worth of pharmacy claims history (April 1, 2009 - June 30, 2009). Members using ACE Inhibitors and ARBs were identified, in addition to members using the combination as defined as two or more consecutive months. Six thousand, nine hundred nineteen (6,919) unique members were identified, of which only 73 met the criteria for further analysis. Just 12 of them

had a diagnosis of congestive heart failure, and nine had diabetes with renal manifestations. The prescribers of the remaining members without a valid diagnosis will be contacted at the request of the Commission.

Ophthalmic Fluoroquinolones and Macrolides for Bacterial Conjunctivitis:

The purpose of this study was to identify instances where Iowa Medicaid members are prescribed ophthalmic fluoroquinolones as first line treatment of bacterial conjunctivitis. Bacterial conjunctivitis is a highly contagious bacterial infection of the eye that affects both adults and children. It is spread by direct contact with infected secretions and contaminated objects. A patient with bacterial conjunctivitis will typically present with redness and discharge from one or both eyes, and is often times described as being "stuck shut" in the morning. A thick, globular, purulent discharge continues throughout the day and may appear yellow, white, or green. The most common organisms responsible for bacterial conjunctivitis include *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. *Staphylococcus aureus* is the most common cause in adults, where other organisms listed are more commonly found in children. The American Academy of Ophthalmology guidelines on treating bacterial conjunctivitis state that "The choice of antibiotic is usually empirical. Since a 5-to-7-day course of a broad-spectrum topical antibiotic is usually effective, the most convenient or least expensive option can be selected." The recommended first line treatment options for bacterial conjunctivitis include erythromycin ophthalmic ointment (particularly for children), sulfacetamide ophthalmic drops, or polymyxin/trimethoprim drops. Most common organisms responsible for bacterial conjunctivitis respond to these agents within one to two days with a marked decrease in discharge, irritation, and redness. Alternative treatments include bacitracin ointment, sulfacetamide ointment, polymyxin/bacitracin ointment, fluoroquinolone drops or azithromycin drops. Aminoglycoside drops are not recommended as they can be toxic to the corneal epithelium and can cause reactive keratoconjunctivitis after several days use. Due to the considerable cost difference between the recommended first line therapy ophthalmic antibiotics, fluoroquinolone drops, and azithromycin drops, it would be most cost effective to initiate therapy with a preferred first line therapy ophthalmic antibiotic drop or ointment. It would be desirable to shift prescribing practices away from fluoroquinolones and azithromycin drops to preferred first line therapy ophthalmic antibiotics, except for cases in which patients have had ocular surgery or are contact lens wearers. An analysis was performed looking at three months worth of pharmacy claims history (March 1, 2009 - May 31, 2009). Members who had claims for fluoroquinolone drops or azithromycin drops without a claim for a preferred first line therapy ophthalmic antibiotic solution/ointment (suggesting that the recommended first line therapy ophthalmic antibiotic product was not tried prior to switching to a fluoroquinolone or azithromycin product after a therapeutic failure) were identified. 94.8% of identified members were using a fluoroquinolone or macrolide ophthalmic antibiotic as first line therapy. Dr. Rick Rinehart motioned that this issue be referred to the P&T Committee, with the hope that they would make ophthalmic fluoroquinolones and macrolides non-preferred on the PDL. Dr. Sara Schutte-Schenck seconded, and the motion passed unanimously.

Rate of Compliance with Atypical Antipsychotics: A medication possession ratio was run on new starters (with continuous Medicaid eligibility during the timeframe of April 1st through June 30th) of an antipsychotic regimen. An NPR of greater than 80% was enough to signify that a patient had sufficient adherence to the therapy. There were 2,958 new starters total, of which 93.5% had sufficient adherence. *Geodon* (ziprasidone), which is dosed twice daily, actually had the highest adherence rate. The Commission asked that a longer time frame (six months minimum) be examined, as well as focusing on quantity and days supply to see where compliance drops off.

Drugs that cause Edema: The purpose of this study was to identify instances where prescribers were prescribing medications that typically cause edema as a side effect in disease states that often have edema present as a symptom. Edema is defined as palpable swelling as a result of interstitial fluid volume expansion. There are many different clinical conditions that can cause edema such as heart failure, cirrhosis, and nephrotic syndrome. Certain medications can also cause edema as a side effect. When used in patients with peripheral edema, the addition of these drugs can cause worsening symptoms of edema such as swollen legs, difficulty walking, increased abdominal girth, and shortness of breath due to pressure on the diaphragm. These patients become high utilizers of prescribers' offices and emergency departments seeking medical care for the discomfort caused by the worsening edema. An analysis was performed to identify instances where prescribers were prescribing medications that typically cause edema as a side effect in Iowa Medicaid members who have disease states that commonly cause edema. The Commission asked that these findings be narrowed down to members who have had a heart failure diagnosis resulting in hospital admission, and take out those already on diuretics.

Tamoxifen Interactions with Select SSRIs: The purpose of this study was to identify instances where members were combining tamoxifen with selective serotonin re-uptake inhibitors (SSRIs). Two observational studies were presented at a meeting of the American Society of Clinical Oncology that looked at the effect of strong CYP2D6 inhibitors in patients taking tamoxifen in preventing recurrence of breast cancer. One of these two studies found that women who took CYP2D6 inhibitors, such as SSRIs, had a higher recurrence rate. Women being treated for breast cancer with tamoxifen are frequently prescribed SSRIs to help manage depression and decrease hot flashes (off label use). Tamoxifen requires metabolism by CYP2D6 to become pharmacologically active. SSRIs such as fluoxetine and paroxetine, are strong inhibitors of CYP2D6. Sertraline is a mild inhibitor of CYP2D6, and citalopram and escitalopram are weak inhibitors of CYP2D6. Since there is no good evidence that one SSRI is more effective than another for treating depression, it may be appropriate to recommend use of citalopram or escitalopram for treatment of depression in women who are also taking tamoxifen. An analysis was done over a three month time period (5-1-09 through 7-31-09) to determine how many women using tamoxifen were also using an SSRI. Of those members identified, a total of 32 (23.4%) were using tamoxifen with an SSRI during the

past three months (5/1/09 through 7/31/09). The prescribers of the 16 members who were identified as using SSRIs that are inhibitors of CYP2D6 in combination with tamoxifen will be contacted, and an article reminding prescribers of this drug-drug interaction will be published in the next DUR Digest.

Miscellaneous

DUR Digest: The Commission members offered suggested changes to the draft for 2009 Volume 22, Number 1.

FUL Update: The Commission members were given a copy of the CMS FUL changes that were implemented August 28, 2009.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 12:00 to adjourn the meeting and move to closed session (1st by Dr. Casey Clor, 2nd by Bruce Alexander).

The next meeting will be held at 9:30 a.m. on Wednesday, November 4, 2009 at the Learning Resource Center in West Des Moines, IA.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes November 4, 2009

Attendees:

Commission Members

Rick Rinehart, M.D.; Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambrosion, R.Ph.; Casey Clor, M.D.; Mark Graber, M.D., FACEP; and Susan Parker, Pharm.D.

Staff

Thomas Kline, D.O.; Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, PA-C, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Mark Graber called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the September 2, 2009 meeting were approved following a spelling correction from Bruce Alexander. (Motion by Bruce Alexander, second by Dr. Sara Schutte-Schenck, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

The re-procurement process is currently underway, with almost all of the IME contracts up for bid. The Department of Human Services is still in the process of finalizing the required budget cuts. Susan Parker reported some of the proposed changes are as follows: The 30-day override for non-preferred drugs on the PDL will be eliminated. The dispensing fee will be lowered to \$4.34, which is a temporary rate cut effective December 1, 2009 through June 30, 2010. There will also be some changes to SMAC, and the way that reimbursement is set; the multiplier for that formula will be decreased from 1.4 to 1.2, and the average acquisition cost based solely on generic pricing now. Additionally, a specialty drug list has been created. AWP Reimbursement for drugs on this list will be AWP minus at a rate > AWP minus 12%. AWP reimbursement methodology will no longer be an option within less than two years, because of the lawsuit regarding First Data Bank. Member coverage has thus far not been affected. However, as the Iowa Medicaid population continues to grow, it will become increasingly difficult to provide benefits with a decreased budget. Lastly, Sandy Pranger reported that the next P&T Committee Meeting will be held November 12th, for the annual PDL review to determine next the PDL for 2010 will occur.

Quarterly Management Report

The average amount paid per claim was down to \$62.52, compared to \$63.59 last quarter; 1,005,342 claims resulted in a total amount paid of \$62,854,354.45. The number of eligible members continues to increase; it was 366,476 in the first quarter of State Fiscal Year 2010. Iowa's unemployment rate was 6.7% in September 2009, which is much lower than the national average of 9.8%. ProAir HFA remains the top drug by number of prescriptions per NDC. The top drugs by dollars spent were all mental health drugs. The therapeutic class by total prescriptions report remained the same as last quarter, with SSRIs in the top spot. The therapeutic class by dollars spent also kept the same line-up, with Atypical Antipsychotics costing \$10,899,841.64. Lastly, generic utilization was up to 70.85% last quarter.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in an annualized total savings of \$2,157.89 pre-rebate (state and federal).

Annual Smoking Cessation Report

The Commission was presented with a copy of the current year's draft report, as well as the finalized report that had been sent to the legislature in 2008. Jeremy Whitaker from the Iowa Department of Public Health was on hand for questions. Quitline received 5,473 fax referrals for Iowa Medicaid members between October 1, 2008 and September 30, 2009, of which 3,339 were enrolled in the program. A total of 9,207 prior authorization requests were received in that same time span for smoking cessation products, of which 6,852 were approved. There were 5,682 prescriptions dispensed, costing just over \$512,000. Of that, Chantix costs alone came to \$402,000. Administration costs totaled \$102,000. The Commission members requested that a report be run to identify any members taking Chantix and antidepressants concurrently. Bruce Alexander recommended searching for any related hospitalizations. A revised report will be brought to the next meeting in December.

Public Comment

Jennifer Stoeffel from Ortho-McNeil Janssen spoke about Nucynta.

PA Criteria

Bupropion SR for Smoking Cessation: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for varenicline (Chantix™) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.*
- 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.*
- 3) Approvals will only be granted for patients eighteen years of age and older.*

- 4) *The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve month period.*
- 5) *Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.*
- 6) *The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.*

Bruce Alexander motioned to accept these criteria, and Dr. Casey Clor seconded. The motion passed unanimously.

Short-Acting Narcotics: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting narcotics. Payment will be considered for cases in which there is documentation of previous trial(s) and therapy failures with three (3) chemically distinct preferred short acting narcotics (based on narcotic ingredient only) at therapeutic doses, unless evidence is provided that the use of these products would be medically contraindicated.

Dr. Casey Clor motioned to accept these criteria, and Bruce Alexander seconded. The motion passed unanimously.

Proton Pump Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is not required for the preferred proton pump inhibitors (PPI) for a cumulative 60 days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization. Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of:

1. *Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).*
2. *Barrett's esophagus.*
3. *Erosive esophagitis*
4. *Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses.*

5. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of *Helicobacter pylori* treatment or a negative *Helicobacter pylori* test result.

Prior authorization is NOT required for Prevacid SoluTabs for children age 8 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid SoluTabs for patients over 8 years of age beginning day one of therapy. Authorization for Prevacid SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Dr. Casey Clor motioned to accept these criteria, and Dr. Sara Schutte-Schenck seconded. The motion passed unanimously.

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis.

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum doses unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, and intramuscular gold.

Prior authorization is required for all non-preferred biologicals for ankylosing spondylitis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

Following a discussion of the "International ASAS Consensus Statement for the use of Anti-Tumor Necrosis Factor Agents in Patients with Ankylosing Spondylitis", Dr. Casey Clor motioned to accept these criteria, and Craig Logemann seconded. The motion passed unanimously.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for arthritis.

Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline.

Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

The Commission members asked that a rheumatologist be contacted for input prior to any changes in prior authorization criteria.

Ketorolac: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ketorolac tromethamine, a nonsteroidal anti-inflammatory drug indicated for short term (up to five days) management of moderately severe, acute pain. It is NOT indicated for minor or chronic conditions.

This product carries a Black Box Warning. Initiate therapy with IV/IM and use oral ketorolac tromethamine only as a continuation therapy to ketorolac tromethamine IV/IM. The combined duration of use of IV/IM and oral is not to exceed five (5) days. Payment will be approved under the following conditions:

- 1. For oral therapy, documentation of recent IM/IV ketorolac tromethamine injection including administration date and time, and the total number of injections given.*

- 2. Request falls within the manufacturer's dosing guidelines. Maximum oral dose is 40mg/day. Maximum IV/IM dose is 120mg/day. Maximum duration of therapy is 5 days per month.*

- 3. Diagnosis indicating moderately severe, acute pain.*

Requests for IV/IM ketorolac must document previous trials and therapy failures with at least two preferred nonsteroidal anti-inflammatory drugs at adequate doses.

As this was the second review of this topic, no motion was necessary. The Commission members had no further comments.

Muscle Relaxants: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred muscle relaxants. Payment for non-preferred muscle relaxants will be authorized only for cases in which there is documentation of previous trials and therapy failures with at least three preferred muscle relaxants. Requests for carisoprodol will be approved for a maximum of

120 tablets per 180 days at a maximum dose of 4 tablets per day when the criteria for coverage are met.

Although a vote was taken, (Dr. Rick Rinehart motioned to accept these criteria, and Larry Ambrosion seconded. The motion passed unanimously.) it was not required as this was the second review and there were no recommended changes.

Antihistamines: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred antihistamines and preferred second generation prescription antihistamines.

Patients 21 years of age and older must have three unsuccessful trials with antihistamines that do not require prior authorization, prior to the approval of a preferred first generation or preferred second generation prescription antihistamine. Two of the trials must be with cetirizine and loratadine. Prior to approval of a non-preferred second generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred second generation prescription antihistamine.

Patients 20 years of age and younger must have unsuccessful trials with cetirizine and loratadine prior to the approval of a non-preferred first generation or preferred second generation prescription antihistamine. Prior to approval of a non-preferred second generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred second generation prescription antihistamine.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Although a vote was taken (Craig Logemann motioned to accept these criteria, and Dr. Sara Schutte-Schenck seconded. The motion passed unanimously.) it was not required as this was the second review and there were no recommended changes.

Fentanyl – Short Acting Oral Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for short acting oral fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients. These products carry a Black Box Warning. Actiq®, Fentora®, & Onsolis™.

- *Are indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain.*
- *Are contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, do not use in opioid non-tolerant patients.*

Although a vote was taken, (Bruce Alexander motioned to accept these criteria, and Dr. Mark Graber seconded. The motion passed unanimously.), it was not required as this was the second review and there were no recommended changes.

Public Comment

There were no speakers in this public comment section.

Focus Studies

TZD plus Congestive Heart Failure: The purpose of this study was to follow-up on the 72 unique members identified as having a diagnosis of CHF while on a TZD during the time frame of 7/1/2008 through 12/31/2008. Letters were sent to providers in March 2009. Fourteen members discontinued a TZD after the DUR intervention. This resulted in a total cost savings of \$136,555.61 (state and federal pre-rebate).

Benzodiazepines without SSRI/SNRI: The purpose of this study was to determine how many Iowa Medicaid members are using alternative mental health drugs instead of selective serotonin reuptake inhibitors (SSRI) or serotonin-norepinephrine reuptake inhibitors (SNRI) in members with panic disorder with agoraphobia, panic disorder without agoraphobia, obsessive-compulsive disorder, and/or dysthymic disorder. At the August 2009 DUR Meeting, a report was generated which looked at members with a diagnosis of panic disorder with agoraphobia, panic disorder without agoraphobia, obsessive-compulsive disorder, and/or dysthymic disorder at anytime in their medical claims history, and what drug therapies (SSRI, SNRI, and/or benzodiazepine) were being prescribed. Due to the high number of members who met these criteria, but showed no current treatment with antidepressants or benzodiazepines (7,225), the Commission was interested in seeing if other mental health drugs and/or anticonvulsants were being used as treatment. Further analysis was done to remove members with a diagnosis code for epilepsy or seizure disorder from the members who fit the diagnostic criteria listed above, who were not being treated with an SSRI, an SNRI, or a benzodiazepine. The pharmacy claims histories for the remaining members were searched over a one year time frame (6/1/08 through 6/30/09) for Antipsychotics - Atypicals, Anticonvulsants (minus clonazepam and *Equetro*), Antidepressants - Tri-Cyclics, Antidepressants - MAOI Inhibitors, Antipsychotics - Typical, and *Buspar*/buspirone. Each member who had two or more fills of one or more drugs from these classes who

then continued therapy into July 2009 were accounted for. One-hundred-sixty-nine unique members were identified as fitting the above criteria. Bruce Alexander pointed out there are a total of 113 members using an antipsychotic and the focus should be on these members for current treatment and additional diagnoses. These findings will be brought to a future meeting.

Lithium Drug-Drug Interactions: The purpose of this study was to identify instances where Iowa Medicaid members are combining lithium with drugs that can potentially interact and cause lithium toxicity. Drug-drug interactions between lithium and ACE Inhibitors, diuretics, NSAIDs, and/or COX-2 Inhibitors are frequently identified on the member-specific profile reviews done for each meeting. Lithium and sodium compete for reabsorption in the kidneys. When sodium is depleted, lithium is reabsorbed at a greater rate and serum lithium levels rise, possibly leading to toxicity. While it is not an absolute contraindication, when lithium is combined with ACE Inhibitors and/or certain diuretics, the depletion of sodium can lead to an increase in serum lithium levels. Similarly, NSAIDs and COX-2 Inhibitors can affect the renal proximal tubular resorption of lithium, thus increasing serum lithium levels. Symptoms of lithium toxicity include ataxia, confusion, and tremor. It is recommended that patients be closely monitored anytime a new drug from the above mentioned classes are added to a lithium regimen for signs and symptoms of lithium toxicity. Close monitoring is also recommended anytime there is a dose change of these products. An analysis was performed looking at paid, non-reversed pharmacy claims over a six month time period (1/1/09 through 6/30/09). Members who had two or more fills for lithium during this time frame were identified. Once those members were identified, a second analysis was done to see how many of these patients were combining lithium with an ACE Inhibitor, a diuretic (loop or thiazide), a blood pressure product combined with a diuretic (i.e. lisinopril HCTZ), an NSAID, or a COX-2 Inhibitor. Those who continued the combination of lithium and a potential interacting drug into the month of July 2009 were selected for review. These findings will be narrowed down to target the prescribers of the 34 members who are receiving their prescriptions from different prescribers, adding in members who are also taking ARBs.

Miscellaneous

DUR Digest: The Commission members were given a completed copy of 2009 Volume 22, Number 1.

FUL Update: The Commission members were given a copy of the CMS FUL changes that were implemented September 25, 2009, as well as SMAC changes that went into effect in October.

MedWatch: The commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 11:20 to adjourn the meeting and move to closed session (1st by Bruce Alexander, 2nd by Dr. Mark Graber).

The next meeting will be held at 9:30 a.m. on Wednesday, December 2, 2009

at the Learning Resource Center in West Des Moines, IA.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes December 2, 2009

Attendees:

Commission Members

Rick Rinehart, M.D.; Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Casey Clor, M.D.; Mark Graber, M.D., FACEP; and Susan Parker, Pharm.D.

Staff

Chad Bissell, R.Ph., Pharm.D.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Chairman Dr. Mark Graber called the meeting to order at 9:30 a.m. at the Learning Resource Center in West Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the November 4, 2009 meeting were approved following a spelling correction from Bruce Alexander. (Motion by Dr. Casey Clor, second by Larry Ambroson, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

There were none.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$6,071.61 pre-rebate (state and federal).

Annual Smoking Cessation Report

The Commission was presented with a copy of the current year's draft report. Their additional recommendations will be added, and a revised report will be brought to the next meeting in February.

MMWR – State Medical Coverage for Tobacco-Dependence Treatments

The Commission members reviewed this report created by the Centers for Disease Control and Prevention (CDC).

Varenicline Safety

Recent varenicline (Chantix) utilization within the Iowa Medicaid program was reviewed to evaluate use in patients with underlying mental health disorders, as

well as those who develop new mental health disorders after starting varenicline. Commission members had expressed interest in this at a previous meeting. They also were curious if these prescribing practices resulted in an increased number of hospitalizations for psychiatric reasons. Additionally, a query was conducted of other state Medicaid programs asking what type of specific criteria restrictions were in place for varenicline when a past history of psychiatric disorders is present or if it is left to the discretion of the prescriber. Seventeen states responded, of which 15 states leave it to the discretion of the prescriber. Two states, Indiana and Washington, have restrictions specific to psychiatric disorders. Indiana currently denies a claim if the member has a diagnosis of depression, suicidal behavior/attempt, or psychosis and has not previously tried both NTR and bupropion in the past two years, unless otherwise contraindicated. Washington has specific criteria based on FDA labeling and denies claims if there is history of a psychiatric disorder. Two analyses were performed looking at paid, non-reversed Iowa Medicaid pharmacy claims over a recent six month time frame (May 1, 2009 through October 31, 2009). The first analysis looked at members who were taking an antidepressant and added varenicline. The second analysis looked at members who started varenicline who then added an antidepressant shortly thereafter. Medical claims were also reviewed during this time to identify how many members required hospitalization for psychiatric illness shortly after starting varenicline. A total of 1,207 unique members were on varenicline during this time frame. One hundred eleven of them added an antidepressant (SSRI, SNRI, TCA, and/or MAOI) after starting varenicline, and three new varenicline starters had a hospitalization for a psychiatric reason. Claims data will be re-evaluated to search for psychiatric breaks and/or mood stabilizing medications, and the prescribers of these 111 members will be contacted.

Public Comment

Nancy Bell from Pfizer spoke about Chantix and fibromyalgia PA criteria. Eric Burns from Alcon Labs spoke about ophthalmic antibiotic criteria changes, and Farid Manshadi, a physician, spoke about Savella and fibromyalgia criteria.

Pro-DUR Edits

Armodafinil – Proposed Age Limit: On August 1, 2007, the DUR Commission voted in favor of following an age restriction per the package insert of modafinil (*Provigil*) restricting use to members 16 years of age and older to prevent off-label use. Since implementation, there have been no issues regarding the age edit on modafinil. There have been several requests for off-label use of the drug in children to treat ADHD. To prevent off label use of armodafinil (*Nuvigil*), it is being proposed to add an age edit to restrict use to members 17 years of age and older. Bruce Alexander motioned to accept this recommendation, and Larry Ambrosion seconded. The motion passed with no objections.

Brand Ophthalmic Fluoroquinolone Products - Proposed Age Edit: The P&T Committee had voted in favor of changing the status of brand ophthalmic fluoroquinolone products to non-preferred for members less than 18 years of

age. This was in response to the DUR Commission's recommendation from September 3, 2009, requesting the P&T Committee consider making all ophthalmic fluoroquinolones non-preferred on the PDL, to shift utilization towards less expensive, first-line treatment options when treating bacterial conjunctivitis since ophthalmic fluoroquinolones are not considered first line options. The DUR Commission disagreed with the P&T Committees recommendation, and again proposed that all ophthalmic fluoroquinolones be non-preferred for children 18 years of age and younger. Dr. Schutte-Schenck suggested DUR staff contact pediatric ophthalmologists to get their opinion on how this will affect their practice. This topic will be taken back to the next P&T Committee meeting.

PA Criteria

Bupropion SR for Smoking Cessation: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for varenicline (Chantix™) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.*
- 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.*
- 3) Approvals will only be granted for patients eighteen years of age and older.*
- 4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.*
- 5) Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.*
- 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.*

No motion was necessary as this was the second review of the topic. The criteria will now be forwarded to the Department of Human Services (DHS).

Proton Pump Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is not required for the preferred proton pump inhibitors (PPI) for a cumulative 60 days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization.

Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of:

- 1. Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).*
- 2. Barrett's esophagus.*
- 3. Erosive esophagitis*
- 4. Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses.*
- 5. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of Helicobacter pylori treatment or a negative Helicobacter pylori test result.*

Prior authorization is NOT required for Prevacid SoluTabs for children age 8 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid SoluTabs for patients over 8 years of age beginning day one of therapy. Authorization for Prevacid SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No motion was necessary as this was the second review of the topic. The criteria will now be forwarded to DHS.

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis.

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum doses unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, and intramuscular gold.

Prior authorization is required for all non-preferred biologicals for ankylosing spondylitis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of a previous trial and therapy failure

with a preferred agent.

No motion was necessary as this was the second review of this topic. The criteria will now be forwarded to DHS.

Short-Acting Narcotics: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting narcotics. Payment will be considered for cases in which there is documentation of previous trial(s) and therapy failures with three (3) chemically distinct preferred short acting narcotics (based on narcotic ingredient only) at therapeutic doses, unless evidence is provided that the use of these products would be medically contraindicated.

No motion was necessary as this was the second review of this topic. The criteria will now be forwarded to DHS.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for arthritis.

Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline.

Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

Dr. Graber volunteered to speak to some rheumatologists to get their input on the new criteria. The topic will then be revisited.

Cymbalta, Lyrica, Savella: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for duloxetine (Cymbalta), pregabalin (Lyrica), and milnacipran (Savella). Payment will be considered under the following conditions:*

- 1. A diagnosis of fibromyalgia (Cymbalta, Lyrica, and Savella)*
 - a. a trial and therapy failure at a therapeutic dose with a tricyclic antidepressant (such as amitriptyline), AND*
 - b. a trial and therapy failure at a therapeutic dose with a preferred muscle relaxant (such as cyclobenzaprine), AND*

- c. at least **two** trials and therapy failures at a therapeutic dose from the following agents: SSRI, tramadol, or gabapentin, **AND**
- d. documented non-pharmacologic therapies (cognitive behavior therapies, exercise etc.), **AND**
- e. documentation of a previous trial and therapy failure at a therapeutic dose with Savella, when Cymbalta and Lyrica are requested.
- 2. A diagnosis of post-herpetic neuralgia (Lyrica)
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, or gabapentin.
- 3. A diagnosis of diabetic peripheral neuropathy (Cymbalta and Lyrica)
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin.
- 4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica)
- 5. A diagnosis of major depressive disorder or generalized anxiety disorder (Cymbalta)

**PA required for new starts only.*

The Commission members thought this wording might be confusing for providers, and had an extensive clinical discussion as to the appropriateness of the criteria. Pam Smith will edit and bring a rearranged version to the next meeting for further deliberation.

DPP-4 Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for dipeptidyl peptidase-4 (DPP-4) inhibitors. Payment will be considered under the following conditions:

- 1) A diagnosis of Type 2 diabetes mellitus,
- 2) Patient is 18 years of age or older,
- 3) The patient has not achieved HbA1C goals using insulin or a combination of two or more antidiabetic medications (metformin, sulfonylurea, or thiazolidinedione) at maximum tolerated doses unless otherwise contraindicated.

Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in HbA1C since the beginning of the initial prior authorization period.

Craig Logemann motioned to accept the proposed criteria, and Bruce Alexander seconded. The motion passed with no objections.

Lidocaine Patch: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for topical lidocaine patches (Lidoderm). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure or contraindications with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin.

In addition, the Commission decided to limit the quantity to 30 for the first fill, and also limit to 90 patches per 30 days. There will be no limit on duration of therapy, however, as post-herpetic neuralgia is a chronic condition. Dr. Casey Clor motioned to accept the proposed criteria and quantity limits. Dr. Rick Rinehart seconded, and the motion passed unanimously.

Ergotamine Derivatives: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for preferred ergotamine derivatives used for migraine headache treatment for quantities exceeding 18 unit doses of tablets, injections, or sprays per 30 days. Payment for ergotamine derivatives for migraine headache treatment beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred ergotamine derivatives beginning the first day of therapy. Payment for non-preferred Ergotamine agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. For consideration, the following information must be supplied:

- 1. The diagnosis requiring therapy.*
- 2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.*

It was proposed that these criteria be removed due to low utilization of this category and higher utilization of Triptans for acute treatment of migraine. For SFY 2009, there was one approved PA out of a total of five PA requests. Six months after removal of the PA, a follow-up will be done to monitor utilization of this drug class. Bruce Alexander motioned to accept the recommendation, and Craig Logemann seconded. All members voted in favor of the motion.

Public Comment

Dr. Geoff Wall spoke about the Biologicals for Arthritis criteria.

Focus Studies

Drugs that cause Edema: The purpose of this study was to identify instances where prescribers were prescribing medications that typically cause edema as a side effect in disease states that often have edema present as a symptom. Edema is defined as palpable swelling as a result of interstitial fluid volume expansion. There are many different clinical conditions that can cause edema

such as heart failure, cirrhosis, and nephrotic syndrome. Certain medications can also cause edema as a side effect. When used in patients with peripheral edema, the addition of these drugs can cause worsening symptoms of edema such as swollen legs, difficulty walking, increased abdominal girth, and shortness of breath due to pressure on the diaphragm. These patients become high utilizers of prescribers offices and emergency departments seeking medical care for the discomfort caused by the worsening edema. An analysis was performed to identify instances where prescribers were prescribing medications that typically cause edema as a side effect in Iowa Medicaid members who have disease states that commonly cause edema. At the September meeting, the Commission had asked that these findings be re-run and remove members who have had a hospital admission for heart failure, and/or those already on diuretics. They reviewed the updated report, but later decided to send letters to all prescribers of members that had appeared in the initial query results.

Abilify for Depression without Antidepressants: The purpose of this study was to determine the extent to which aripiprazole (*Abilify*) is being used as monotherapy to treat major depression. Aripiprazole is an atypical antipsychotic that was first approved for use in schizophrenia in 2002. Unlike other atypical antipsychotics that bind to D₂ receptors in the nigrostriatal pathway, aripiprazole acts as a partial agonist at the D₂ receptors. In 2008, the FDA approved the use of aripiprazole as adjunctive treatment of major depressive disorder. This indication was based on two short-term (6 weeks) placebo-controlled trials of adult patients who met the DSM-IV criteria for MDD who had an inadequate response to venlafaxine ER, paroxetine CR, fluoxetine, escitalopram, or sertraline. In both trials, aripiprazole was superior to placebo in reducing the mean Montgomery-Asberg Depression Rating Scale scores. At a recent DUR Commission meeting, some concern was expressed as to the possibility that providers were using aripiprazole to treat MDD as monotherapy instead of as adjunctive therapy. This was based on observations made during profile reviews and observations in practice. An analysis was performed looking at paid pharmacy claims over a six month time period (3/1/09 through 8/31/09) to identify members using aripiprazole with and without SSRIs or SNRIs concurrently. For those identified as using aripiprazole as monotherapy, anyone with a diagnosis for schizophrenia or bipolar disorder was removed. Concurrent therapy was defined as having two or more fills for aripiprazole while also receiving prescriptions for an SSRI or an SNRI. Three thousand seventy-eight unique members were using aripiprazole for depression, of which 1,974 used a SSRI or SNRI in combination, and 1,104 (36%) were using aripiprazole (*Abilify*) as monotherapy. Forty-three of those 1,104 members were using a drug from the Tricyclic Antidepressant or MAO Inhibitor PDL category. The Commission asked that the report be rerun to look for GAD, mood stabilizers, and second-generation antipsychotics as well.

Chronic Use of Transdermal Scopolamine: The purpose of this study was to determine the extent to which Iowa Medicaid members are using transdermal scopolamine (*Transderm Scōp*) on a chronic basis and/or in combination with oral medications. Transdermal scopolamine is a belladonna alkaloid that is FDA

indicated to prevent motion sickness and nausea and vomiting associated with anesthesia following surgery. It is compendia indicated for excessive salivation. Transdermal scopolamine is a small flat patch that is applied behind the ear at least four hours before the prevention of nausea and vomiting is required, typically four hours before travel. Transdermal scopolamine comes in boxes of four patches, and each patch lasts for 3 days. The most common use for transdermal scopolamine is to prevent motion sickness prior to air, car, or boat travel. Transdermal scopolamine is a preferred product on the Preferred Drug List, and is not subject to clinical prior authorization criteria, quantity limits, or ProDUR edits of any kind. Based on marketshare data for State Fiscal Year 2009, there were 659 prescriptions billed for *Transderm Scōp* for an average of 6 units per prescription at a cost of \$50.82 (state and federal dollars, pre-rebate) per prescription. When compared to other therapies used for motion sickness, this average cost per prescription is considerably higher due to SMAC prices on the other products. For example, the average cost per prescription for meclizine is \$5.64 (state and federal dollars, pre-rebate) for an average of 52 tablets per prescription. Through the usual course of profile reviews, it has been noticed there are members using transdermal scopolamine on both a regular basis and in combination with other oral medications. To evaluate the extent of this practice, an analysis was done over a three month timeframe (7/1/09 through 9/30/09) to determine how many members were using transdermal scopolamine chronically, who had previous trials with meclizine, who was taking other oral medications, and who was receiving quantities greater than four. Twenty-eight unique members had more than two fills on the claim histories. This data will be rerun to remove cancer patients, and then letters will be sent to the prescribers involved.

Long-Term Use of Short-Acting Opioids: The purpose of this study was to determine the number of members using four or more doses per day of a short acting opioid for an extended period of time without using a long acting opioid. Potential benefits of switching to a long acting opioid in chronic non-cancer pain could provide members with a more consistent control of pain, improved adherence, and lower risk of addiction or abuse. There are no clear guidelines for use of short-acting opioids versus long-acting opioids, as there is insufficient evidence comparing the two. There is a lack of studies that support a recommendation of as-needed versus around-the-clock dosing of opioids. The decision to switch to a long-acting opioid should be based on outcomes of a trial with a short-acting opioid lasting several weeks to a few months. An example of outcomes to consider would include progress toward meeting therapeutic goals, presence of adverse effects, changes in the underlying pain condition, changes in psychiatric or medical comorbidities, identification of aberrant drug-related behaviors, addiction, or diversion. It is important to note that although neuropathic and non-neuropathic pain conditions appear to respond to chronic use of long-acting opioids, evidence that supports efficacy of these products for conditions such as chronic low back pain, daily headache, and fibromyalgia are lacking. An analysis was preformed looking at paid pharmacy claims over a six month time period (4/1/09 through 9/30/09). Members who had four or more doses per day for 90 days or longer of any drug from the Narcotics -

Miscellaneous PDL category without claims for any drug in the Narcotics - Long Acting PDL category during the same time period were identified. If members are using short-acting opioids on a chronic basis for non-cancer pain, it is thought that they should be considered for a trial with a preferred long-acting opioid. One thousand three hundred five members were identified as using four or more doses of a short-acting opioid per day for more than 90 days without claims for a long-acting narcotic. Their average length of therapy was five months. Letters will be sent to prescribers with patients on two or more short-acting opioids. If Maine's new restrictive PA criteria (members having 90 days of opiates in the past 100 days would require a PA to ensure appropriate indication, non-pharmacologic and non-opioid treatments have been considered and/or tried, an opiate/controlled substance contract exists, and review of a monitoring plan, i.e. urine drug screens and pill counts, if necessary) for this category proves effective, it could possibly be adopted in Iowa in the future.

Miscellaneous

SMAC Update: The Commission members were given a copy of the SMAC changes effective November 25, 2009.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 12:04 p.m. to adjourn the meeting and move to closed session (Motion by Bruce Alexander, second by Craig Logemann).

The next meeting will be held at 9:30 a.m. on Wednesday, February 3, 2010 at the Learning Resource Center in West Des Moines, IA.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes February 3, 2010

Attendees:

Commission Members

Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Casey Clor, M.D.; and Susan Parker, Pharm.D.

Staff

Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Vice-Chairperson Laurie Pestel called the meeting to order at 9:30 a.m. at the Learning Resource Center in West Des Moines. Commission members and guests were welcomed and introduced.

The minutes from the December 2, 2009 meeting were approved following several corrections from Commission members. (Motion by Bruce Alexander, second by Larry Ambroson, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

Vendors bidding for IME contracts gave oral presentations to DHS last week. Decisions should be announced to the public next week. With the contract re-negotiation, there will only be 6 DUR meetings per year, every other month, starting in August. The next P&T Meeting will be April 8th at the Botanical Center in Des Moines.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$17,791.48 pre-rebate (state and federal).

Quarterly Management Reports (Summary)

For the second quarter of State Fiscal Year 2010, the average amount paid per claim was \$59.81, which was a subtle decrease from the previous quarter. Total dollars paid for the quarter was up to \$64.2 million. The number of paid claims, along with the number of eligible members, also continues to trend upwards. There were 373,114 eligible Medicaid members in the second quarter. The average number of claims per utilized member was 5.39, and percent of controlled substances was 18.67%. *ProAir HFA* (albuterol) continues to be the top drug by number of prescriptions, and *Synagis* (palivizumab) was the top drug

by dollars spent. Brand single source drugs made up 22.87% percent of paid claims, while generic utilization was up to 72.11%. Lastly, the average amount paid per generic claim was \$13.09.

Annual Smoking Cessation Report

The Commission was presented with a copy of the current year's draft report, which had been updated with their additional recommendations from the last meeting. Larry Ambrosion motioned that this finalized version be forward to the Department of Human Services. Craig Logemann seconded, and the motion passed with no objections.

Public Comment

Rose Mullen, Outcome Liaison Consultant and Dr. Donna Bahls, Lecture Bureau Speaker, representing Eli Lilly spoke of *Cymbalta* and fibromyalgia PA criteria. Nancy Bell from Pfizer spoke about fibromyalgia PA criteria. Kristin Crouch from Forest Labs spoke about *Savella* and fibromyalgia criteria. Sarah Sullivan from Merck reviewed the American Association of Clinical Endocrinologists consensus statement regarding DPP-4 Inhibitors.

Pro-DUR Edits

Armodafinil – Proposed Age Limit: On August 1, 2007, the DUR Commission voted in favor of following an age restriction per the package insert of modafinil (*Provigil*) restricting use to members 16 years of age and older to prevent off-label use. Since implementation, there have been no issues regarding the age edit on modafinil. There have been several requests for off-label use of the drug in children to treat ADHD. To prevent off label use of amodafinil (*Nuvigil*), it is being proposed to add an age edit to restrict use to members 17 years of age and older. This was the second review of this topic, and the Commission had no further comments. This will now be forwarded to DHS.

PA Criteria

PEG 3350 Utilization: Pam Smith followed up on the days supply edit that had been placed on PEG 3350 to allow for the colonoscopy in children. A review of claims for the past six months identified only one member using this drug for something other than a colonoscopy. Calls were made to the pharmacy and the doctor's office, and they've been asked to correct this. It has not been filled since November 2009.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for arthritis.

Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline.

Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

DPP-4 Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for dipeptidyl peptidase-4 (DPP-4) inhibitors. Payment will be considered under the following conditions:

- 1) A diagnosis of Type 2 diabetes mellitus,*
- 2) Patient is 18 years of age or older,*
- 3) The patient has not achieved HbA1C goals using a combination of two or more antidiabetic medications (metformin, sulfonylurea, thiazolidinedione, or insulin) at maximum tolerated doses unless otherwise contraindicated.*

Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in HbA1C since the beginning of the initial prior authorization period.

As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

Lidocaine Patch: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for topical lidocaine patches (Lidoderm). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

In addition, the commission decided to limit the quantity to 30 patches for the first fill, and also limit to 90 patches per 30 days. There will be no limit on duration of therapy, however, as post-herpetic neuralgia is a chronic condition. As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

Ergotamine Derivatives: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for preferred ergotamine derivatives used for migraine headache treatment for quantities exceeding 18 unit doses of tablets, injections, or sprays per 30 days. Payment for ergotamine derivatives for migraine headache treatment beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred ergotamine derivatives beginning the first day of therapy. Payment for non-preferred Ergotamine agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. For consideration, the following information must be supplied:

- 1. The diagnosis requiring therapy.*
- 2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.*

It was proposed that these criteria be removed due to low utilization of this category and higher utilization of Triptans for acute treatment of migraine. For SFY 2009, there was one approved PA out of a total of 5 PA requests. Six months after removal of the PA, a follow-up will be done to monitor utilization of this drug class. As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

Cymbalta, Lyrica, Savella: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for duloxetine (Cymbalta), pregabalin (Lyrica), and milnacipran (Savella). Payment will be considered under the following conditions:

- 1. A diagnosis of fibromyalgia (Cymbalta, Lyrica, and Savella)
 - a. a trial and therapy failure at a therapeutic dose with three drugs from any of the following: tricyclic antidepressant, muscle relaxant, SSRI, tramadol or gabapentin, **WITH***
 - b. documented non-pharmacologic therapies (cognitive behavior therapies, exercise etc.), **AND***
 - c. documentation of a previous trial and therapy failure at a therapeutic dose with Savella, when Cymbalta and Lyrica are requested.**
- 2. A diagnosis of post-herpetic neuralgia (Lyrica)
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, valproate, carbamazepine, or gabapentin.*
- 3. A diagnosis of diabetic peripheral neuropathy (Cymbalta and Lyrica)
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin.*

4. *A diagnosis of partial onset seizures, as adjunct therapy (Lyrica)*
5. *A diagnosis of major depressive disorder or generalized anxiety disorder (Cymbalta)*

The Commission members thought the preferred medications should be listed on the PA form for the convenience of prescribers. The draft PA form will be brought to the next meeting.

Public Comment

There were no speakers in this public comment section.

Focus Studies

Abilify for Depression without Antidepressants: The purpose of this study was to determine the extent to which aripiprazole (*Abilify*) is being used as monotherapy to treat major depression. At a recent DUR Commission meeting, some concern was expressed as to the possibility that providers were using aripiprazole to treat MDD as monotherapy instead of as adjunctive therapy. This was based on observations made during profile reviews and observations in practice. An analysis was performed looking at paid pharmacy claims over a six month time period (3/1/09 through 8/31/09) to identify members using aripiprazole with and without SSRIs or SNRIs concurrently. For those identified as using aripiprazole as monotherapy, anyone with a diagnosis for schizophrenia or bipolar disorder was removed. Concurrent therapy was defined as having two or more fills for aripiprazole while also receiving prescriptions for an SSRI or an SNRI. A total of 3,078 unique members were identified as using aripiprazole for depression, of which 1,974 used a SSRI or SNRI in combination, and 1104 (36%) were using aripiprazole (*Abilify*) as monotherapy. Forty-three of those 1,104 members were using a drug from the Tricyclic Antidepressant or MAO Inhibitor PDL category. At the December 2009 DUR meeting, it was requested the data be re-run, removing members with a diagnosis of generalized anxiety disorder, members using a mood stabilizer (lamotrigine, levetiracetam, divalproex, carbamazepine, topiramate, oxcarbazepine, and/or lithium), and to look to see if other antipsychotic medications are being used. Of the 1,104 members originally identified in the initial study, only 1,006 members were currently eligible when the data was re-run. One-hundred-sixty-four (164) of these members were identified as not meeting any of the criteria for use of aripiprazole (*Abilify*) based on their medical claims data. Letters will be sent to their prescribers. Dr. Casey Clor suggested that they be reminded that *Abilify* is very expensive compared to other alternatives. The letter could suggest other more cost efficient options they might prescribe instead.

Off-Label Utilization of Cholinomimetics: The purpose of this study was to determine the extent to which drugs approved for the treatment of Alzheimer's dementia are being used for off-label indications. In June 2007, the DUR Commission recommended to the Department that an age edit be placed on the cholinomimetic drugs used for Alzheimer's dementia due to the high prevalence

of off-label use in young members for diagnoses such as traumatic brain injury and autism. Since July 30 2007, claims for members under 40 years of age have required a prior authorization. These have been dealt with on a case-by-case basis. For those over 40 years of age, claims for cholinomimetics, specifically *Aricept* (donepezil) and *Namenda* (memantine), which are preferred drugs on the Preferred Drug List, have paid without a review of the member's diagnosis. Both drugs have been used off label in the treatment of attention-deficit/hyperactivity disorder (ADHD); behavioral syndromes in dementia; Lewy body dementia; treatment of mild-to-moderate vascular dementia; mild cognitive impairment; traumatic brain injury; autism; and stroke. A pharmacy claims analysis was performed looking at paid, non-reversed pharmacy claims between 6-1-09 and 11-30-09. Members who had two or more claims for *Aricept* (donepezil) and/or *Namenda* (memantine) were identified. A search of these members' medical claims histories was done to look for diagnosis codes corresponding with Alzheimer's dementia, dementia (senile, pre-senile, vascular, etc), amnesic disorder, and frontotemporal dementia. One-hundred-fifteen (115) unique members met the search criteria. Eighty-five (85) of them were found to have an off-label diagnosis in their pharmacy claims history. Their prescribers will be contacted. This topic will also appear as an article in an upcoming DUR Digest under a "dementia" header as requested.

Utilization of Multiple Oral Anti-Diabetic Agents without Use of Insulin: The purpose of this study was to determine the number of members using three or more oral anti-diabetic medications concurrently. Based on observations made during member-specific profile reviews, it was suspected that many Iowa Medicaid members with type 2 diabetes were prescribed multiple oral anti-diabetic products in various combinations as opposed to adding insulin after one or two oral medications failed to achieve glycemic goals. An analysis was performed looking at paid pharmacy claims over a three month time period (9/1/09 through 11/30/09). Members who were using multiple oral anti-diabetic agents were identified. Seventy-eight (78) unique members were identified as using 3 or more anti-diabetic active ingredients concurrently. None of them were taking insulin, and only 2 had claims for Byetta in their profiles. Letters will be sent to the prescribers of members on 4 or 5 anti-diabetic agents concurrently. This topic will also appear as an article in the DUR Digest.

Cholesterol-Lowering Medication Pre- and Post-MI: The purpose of this study was to determine the extent to which members at high risk for coronary heart disease events are being treated for dyslipidemia, and of those being treated, how compliant these members are with their drug regimen. Similar to other studies that have been performed by the Iowa DUR Commission looking at adherence to professional guidelines for post-MI patients, we were interested in looking to see how many Iowa Medicaid Members were being treated with a cholesterol lowering agent following a new diagnosis of MI, unstable angina, and/or acute coronary syndrome. Additionally, the report showed how compliant those members were with their medication regimen. A report was run looking at Iowa Medicaid members who had constant eligibility between 12/1/06 and 11/30/09. An analysis of their pharmacy claims history and medical claims history

were preformed during this time period. Within the members' medical claims histories, we identified members who had new diagnoses of myocardial infarction, unstable angina, and/or acute coronary syndrome between 12/1/07 and 11/30/08. The drugs that were searched included drugs and drug combinations that can be used for lowering cholesterol (statins, fibrates, and niacin) as recommended by multiple professional guidelines. For those members we identified as using cholesterol lowering pharmacotherapy, a medication possession ratio (MPR) was performed to assess compliance. Twelve (12) members were identified as having used cholesterol-lowering medications prior to an episode, but then discontinued following the episode. Dr. Casey Clor asked that the data be rerun to focus on members with these diagnoses in their claims files but who were not taking a statin medication. The 3-year eligibility timeframe will not be used for the new data pull. Craig Logemann asked if it would be possible to obtain national data, for a benchmark comparison. The Commission decided to hold off on letters for now and discuss with Dr. Kline at the next meeting the possibility of the IME nurse care managers supervising these members in the future.

Antiviral Utilization: Commission members were provided with utilization data and trend charts for Tamiflu and Relenza usage between 9/1/09 and 11/30/09. The peak appeared to have occurred between 10/11/09 and 10/25/09. The week of 10/18/09 had the highest number of prescriptions: 1,998 for Tamiflu, and 15 for Relenza, for a total of 2,013. Polk County had the most members on antivirals during this time period: 644. The Commission members agreed that no further action was needed for this focus study.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 2.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 11:18 to adjourn the meeting and move to closed session (1st by Bruce Alexander, 2nd by Craig Logemann).

The next meeting will be held at 9:30 a.m. on Wednesday, March 3, 2010 at the Learning Resource Center in West Des Moines, IA.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes March 3, 2010

Attendees:

Commission Members

Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambrosio, R.Ph.; Rick Rinehart, M.D.; and Casey Clor, M.D.

Staff

Thomas Kline, D.O.; Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Vice-Chairperson Laurie Pestel called the meeting to order at 9:36 a.m. at the Learning Resource Center in West Des Moines. Commission members and guests were welcomed and introduced.

The minutes from the February 3, 2010, meeting were approved. (Motion by Bruce Alexander, second by Dr. Sara Schutte-Schenck, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

The next P&T Meeting will be April 8th at the Botanical Center. Pam Smith recently attended the 3-day ADURS meeting for pharmacists specializing in medication utilization within state Medicaid populations. Dr. Kline summarized the most recent Clinical Advisory Committee meeting. They addressed utilization criteria (this will now be done annually for all PA processes at the IME); the new PA process for elective outpatient CT, MRI, and PET scans which became effective March 1st; and revised MediPass reports. There will be some small changes to the new IME vendor contracts. DHS Director Charles Krogmeier has assembled a task force regarding people with dual diagnoses of behavioral health disorders and other health issues, specifically that many of them have been discharged only to be readmitted. It is felt an intervention is needed to reduce such instances. Dr. John Kalachnik, chairman of the aforementioned taskforce, spoke in depth of their efforts to educate providers, as well as their pharmacotherapy recommendations. He was also asked to speak at the April 8th P&T Meeting.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of \$1,353.69 pre-rebate (state and federal).

Public Comment

Nicole Griswold from Shire Pharmaceuticals spoke about Intuniv.

PA Criteria

Cymbalta, Lyrica, Savella: The Commission reviewed the prior authorization criteria as follows:

Prior Authorization is required for duloxetine (Cymbalta[®]), pregabalin (Lyrica[®]), and milnacipran (Savella[™]). Payment will be considered under the following conditions:

1. *A diagnosis of fibromyalgia (Cymbalta[®], Lyrica[®], and Savella[™])*
 - a. *a trial and therapy failure at a therapeutic dose with three drugs from any of the following: tricyclic antidepressant, muscle relaxant, SSRI, tramadol, or gabapentin, **WITH***
 - b. *documented non-pharmacologic therapies (cognitive behavior therapies, exercise etc.), **AND***
 - c. *documentation of a previous trial and therapy failure at a therapeutic dose with Savella[™], when Cymbalta[®] and Lyrica[®] are requested.*
2. *A diagnosis of post-herpetic neuralgia (Lyrica[®])*

The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, valproate, carbamazepine, or gabapentin.
3. *A diagnosis of diabetic peripheral neuropathy (Cymbalta[®] and Lyrica[®])*

The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin.
4. *A diagnosis of partial onset seizures, as adjunct therapy (Lyrica[®])*
5. *A diagnosis of major depressive disorder or generalized anxiety disorder (Cymbalta[®])*

The Commission members offered a few changes to the PA form itself, specifically to the listed drug trial examples and their order. Sandy Pranger suggested that a caveat might be added to the form to notify providers that these trials could be found on the web site as well. Craig Logemann thought maybe each disease state should be labeled as a section, so prescribers knew they did not have to fill out the entire form. The possibility of breaking this up into multiple PA forms, one per diagnosis, was also discussed. Bruce Alexander motioned to accept the criteria wording (no final decision was made on the number of forms), and Dr. Rick Rinehart seconded. The motion passed with no objections or abstentions.

Extended Release Guanfacine (Intuniv): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Intuniv. Payment will be considered for patients when the following is met:

- 1) The patient is between 6 and 17 years of age with a diagnosis of ADHD;*
- 2) Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant, as well as a*
- 3) Previous trial and therapy failure at a therapeutic dose with Strattera, and a*
- 4) Previous trial and therapy failure at a therapeutic dose with immediate release guanfacine.*

A quantity limit of 30 tablets per 30 days for all strengths (1mg, 2mg, 3mg, and 4mg) was also recommended. Pam Smith read through criteria that had been implemented in other state programs. Bruce Alexander motioned to hold off on establishing criteria for this drug until the May meeting, as this is a new drug and it is on the agenda for the April 8th P&T meeting. Craig Logemann seconded, and the motion passed unanimously.

Public Comment

There were no speakers in this public comment section.

Focus Studies

ACE Inhibitors Combined with Angiotensin Receptor Blockers: The purpose of this study was to follow-up on the 47 unique members identified as using an Angiotensin Converting Enzyme (ACE) Inhibitor in combination with a Angiotensin Receptor Blocker (ARB), without a diagnosis of congestive heart failure, in their claims history during the time frame 4/1/09 to 6/30/09. Letters were sent to providers in October 2009. Twenty-six members discontinued medications following the DUR intervention, which resulted in \$5,414.25 in cost savings (state and federal pre-rebate).

Utilization Patterns of Cholesterol-Lowering Medication Pre- and Post-MI: The purpose of this study was to determine the extent to which members at high risk for coronary heart disease events are being treated for dyslipidemia and of those being treated, how compliant these members are with their drug regimen. A report was presented at the February meeting looking at Iowa Medicaid members who had constant eligibility between 12/1/06 and 11/30/09 who had new diagnoses of myocardial infarction, unstable angina, and/or acute coronary syndrome between 12/1/07 and 11/30/08. A search of these members' pharmacy claims histories was also performed looking for drugs and drug combinations that can be used for lowering cholesterol (statins, fibrates, and niacin) as recommended by multiple professional guidelines. A total of 222 unique members had constant eligibility between 12/1/06 and 11/30/09 with a new diagnosis of myocardial infarction, unstable angina, and/or acute coronary

syndrome between 12/1/07 and 11/30/08. After reviewing these data, a suggestion was made to look at current data from 2009 for new events. For the new data set, medical and pharmacy claims data between 1/1/2009 and 12/31/2009 were reviewed. Members who had a new diagnosis of myocardial infarction, acute coronary syndrome, and/or unstable angina were identified. Of these members, a review of their pharmacy claims history was done looking for cholesterol lowering drugs. Of these 243 members identified, 127 (52.3%) were found to be on a cholesterol lowering agent following this diagnosis. The majority of these members were on a statin; most of these members were using simvastatin. Letters will be sent to the providers of the 116 members not using a cholesterol lowering drug to inquire if the member has been managed successfully with lifestyle modifications and request they reconsider the member's risk factors for a recurrent CHD event if the member has not been successful at getting to their lipid goals.

Proton Pump Inhibitors Plus Clopidogrel (Plavix): The purpose of this study was to re-review Iowa Medicaid Members using clopidogrel (*Plavix*) for two or more consecutive months between 11/1/09 and 1/31/10 that are also using a proton pump inhibitor. In June 2009, the DUR Commission looked at reports suggesting that omeprazole and other proton pump inhibitors (PPIs) could interfere with the antiplatelet effect of clopidogrel (*Plavix*). Clopidogrel is a prodrug that is activated by CYP450 enzymes in the liver primarily by CYP2C19. All PPIs may inhibit CYP2C19 to some extent, with omeprazole being a strong inhibitor of CYP2C19; pantoprazole (*Protonix*) appears to be the weakest inhibitor. It was indicated at that point in time more data was needed to clarify the clinical significance of the interaction between clopidogrel and PPIs. On November 17th, 2009, the Food and Drug Administration (FDA) published an alert with updated data regarding this interaction. The FDA stated that the therapeutic effect of clopidogrel on platelets was reduced by as much as 47% in persons receiving clopidogrel and omeprazole together due to a reduction in the active metabolite of clopidogrel by about 45%. Additionally, separating the dose of each drug did not seem to impact the interaction. When the language concerning this interaction was intensified by the FDA, the Commission recommended a re-review of the data. Within the Iowa Medicaid population, the following utilization data was observed during a two month time period (11/1/2009 through 12/31/2009). Seventy-two members were using *Plavix* plus any PPI, but only 2 of them continued this combination into January. Thirteen members were using *Plavix* plus omeprazole, but none of them were still using this combination in January. Since the combined utilization is trending downward, and a DUR Digest article has already been published, the Commission thought an additional intervention was not necessary.

Atypical Antipsychotics plus Anticholinergics: The purpose of this study was to determine the incidence of atypical antipsychotics used in combination with anticholinergics to manage extrapyramidal side effects (EPS). Extrapyramidal

side effects consist of six syndromes that can be considered reversible (acute dystonia, akathisia) which occur within a few hours to days, or days to weeks (parkinsonism, neuromalignant syndrome), and potential irreversible hyperkinetic movement that occurs after several months to years of therapy (tardive dyskinesia, focal perioral tremor). EPS is a common side effect when older, first generation antipsychotics are used. Often times, first generation antipsychotics would need to be combined with anticholinergic medications, such as benztropine, trihexyphenidyl, or diphenhydramine, to reduce the severity of EPS. However, these side effects are further minimized when using newer, atypical antipsychotics. When used in multiple combinations and/or at higher than recommended doses, the beneficial side effect profile of atypical antipsychotics is often reduced and patients experience EPS. When EPS occur in patients taking atypical antipsychotics, such that treatment is required, one could question whether there is truly a benefit in using a more expensive atypical antipsychotic when perhaps a first generation antipsychotic could be used instead. A report was generated looking at pharmacy claims histories from 10-1-09 through 12-31-09 for members who had two or more fills for any drug within the PDL category; Antipsychotics – Atypical. Members using anticholinergic medications to treat EPS were then identified. Of these 8,198 members, 692 members also had claims for benztropine, trihexyphenidyl, and/or diphenhydramine. The Commission decided to refer this topic to the Mental Health Advisory Group.

Antipsychotic Utilization in Children & Adolescents 2005 vs. 2009 and Duplicate Antihistamines: Bruce Alexander motioned that these two focus study topics be tabled until the May meeting given the time constraints. Dr. Rick Rinehart seconded, and the decision was unanimous.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 2.

SMAC Updates: The Commission members were given a copy of the SMAC changes effective March 4, 2010.

MedWatch: The commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 11:55 to adjourn the meeting and move to closed session (1st by Craig Logemann, 2nd by Bruce Alexander).

The next meeting will be held at 9:30 a.m. on Wednesday, May 5, 2010 in Room 116 at the State Capitol in Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes May 5, 2010

Attendees:

Commission Members

Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambrosion, R.Ph.; Rick Rinehart, M.D; Susan Parker, Pharm.D.; and Mark Graber, M.D., FACEP.

Staff

Thomas Kline, D.O.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Chairperson Dr. Mark Graber called the meeting to order at 9:31 a.m. in Room 116 at the State Capitol in Des Moines. Commission members and guests were welcomed and introduced.

The minutes from the March 3, 2010 meeting were approved. (Motion by Dr. Richard Rinehart, second by Craig Logemann, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

As of July 1, 2010, a new vendor will be overseeing the Disease Management and Care Management programs, so there will be some changes to the daily workload within the Medical Services Unit. The high-tech radiology program is moving forward, however; prior authorizations are now being processed for outpatient CTs, MRIs, and PET scans. Providers are getting accustomed to this PA process, despite the lack of pre-implementation education due to time constraints resulting from the budget crisis. Medical Services is currently going through a URAC accreditation process as well. The Iowa Care Expansion program, effective 10-1-10, will increase the budget for Iowa Care and allow for 2 more primary care location options (in Council Bluffs and Sioux City prospectively) for members in addition to Broadlawns and the University of Iowa, which are their only current options for treatment. In 2014 when Healthcare Reform goes into effect, this Iowa Care program will cease to exist as it will be included into the Medicaid Expansion. Healthcare Reform is going to have some effects on State Medicaid programs, especially the pharmaceutical aspects. The Federal Government has imposed additional minimum rebate requirements to the manufacturers, but all of that will go back to the Federal Government. That will change the perspective on what a drug's real net pricing is; the State and Federal points of view on this will differ substantially. Another aspect of Healthcare Reform is that new formulations will require the same rebate as the existing forms. This will cut into the supplemental rebate revenue significantly, and goes retroactive back to 1-1-10. Also, the Iowa Code previously excluded certain categories of medications from being included on the

Preferred Drug List, including those used for mental illness. However, the Legislature removed that exemption this session so medications used in the treatment of mental illnesses will be subject to preferred and non-preferred status rather than just being on the Recommended Drug List, effective January 1, 2011. Anyone established on a mental health drug up to that point would be grandfathered. Any mental health drug requiring prior authorization will be eligible for a 7-day supply while obtaining prior authorization, as opposed to the 3-day supply currently allowed for all other products.

Quarterly Management Reports

The average amount paid per claim was \$59.87 for the last quarter. 1,065,956 claims paid out a total of \$63,820,590.81 for the 379,425 eligible members. 74.40% of these claims were for generic medications, and 18.59% were for controlled substances. ProAir HFA continued to have the highest number of prescriptions, while the largest amount of money (\$5,119,146.43) was spent on Synagis.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of \$2,442.59 pre-rebate (state and federal).

Public Comment

Karen Loihl from the Iowa Psychiatric Society voiced concerns regarding the proposed prior authorization criteria for *Intuniv*.

PA Criteria

Extended Release Formulations: At the March DUR meeting, while discussing the proposed PA criteria for extended release guanfacine, it was suggested that the language for the Extended Release Formulations PA criteria be re-evaluated. Specifically, the commission questioned if there needs to be a therapy failure with the immediate release product, or if it would be more appropriate if the patient showed some therapeutic benefit from the immediate release product. The current language reads:

Payment for a non-preferred extended release formulation will be considered only for cases in which there is documentation of previous trial and therapy failure with the preferred immediate release product of the same chemical entity, unless evidence is provided that use of the immediate release product would be medically contraindicated.

*Prior authorization is required for the following extended release formulation(s):
Adoxa, Amrix, Cardura XL, Cipro XR, Coreg CR, Doryx, Flagyl ER, glipizide er,
Glucotrol XL, Luvox CR, metronidazole sr, Prozac Weekly, Requip XL, Ryzolt,
Seroquel XR, Solodyn ER, tramadol sr, Ultram ER.*

The Commission members agreed that these criteria needed to be changed. They suggested adding in "the member has shown improvement on the immediate release medication, but does not tolerate due to side effects" and requiring a trial of another

drug in the same category. Pam Smith will revise the wording and bring it to the June meeting.

Cymbalta, Lyrica, Savella: At the March meeting, the Commission reviewed a draft PA form for *Cymbalta, Lyrica, and Savella* and requested the form be split into three different PA forms for each drug. After discussion with the PA Department, it was felt that the PA form should not be split. The Commission reviewed the draft PA form with some modifications.

No motion was necessary as this had been discussed prior to this meeting, and no further changes were made. The Commission members did request, however, that a search function be added to the PDL website, so that forms (especially ones like this used for multiple drugs) could be found more easily. This capability might be added in the future, depending on programming requirements.

Extended Release Guanfacine (Intuniv): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Intuniv. Payment will be considered for patients when the following is met:

- 1) The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
- 2) Previous trial and therapy failure at a therapeutic dose with immediate release guanfacine; and*
- 3) Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant; and*
- 4) Previous trial and therapy failure at a therapeutic dose with Strattera.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

A quantity limit of 30 tablets per 30 days for all strengths (1mg, 2mg, 3mg, and 4mg) was also recommended. Susan Parker noted that the age restrictions were most likely unalterable (as Dr. Wadle had commented that many prescribers were wanting to use it on children younger than 6), because they needed to match the FDA standards due to Healthcare Reform allowing for more federal scrutiny about use of mental health drugs and PA criteria. Craig Logemann would also like to revise the second bullet point, stating a requirement for "previous trial with inadequate response or intolerance with therapeutic dose of the immediate release guanfacine". This topic was referred to the Mental Health Advisory Group.

Public Comment

James Osborn from GlaxoSmithKline spoke about DHS' educational efforts in regards to Beta Agonists used for Asthma. Lisa Goetz from Medimmune spoke about Synagis.

Focus Studies

Tamoxifen Interactions with Select SSRIs: The purpose of this study was to follow-up on the 16 unique members identified as using tamoxifen in combination with an SSRI that is a strong or mild inhibitor of CYP2D6 during the time frame 05/01/09 to 07/31/09. Letters were sent to providers in October 2009. Medication discontinuations resulted in \$257.28 in savings (state and federal pre-rebate). This was just a follow-up discussion, so no further action was taken.

Antipsychotic Utilization in Children & Adolescents 2005 versus 2009: The purpose of this study was to compare mental health drug utilization in children between 2005 and 2009. The "Kids Getting Anti-Psychotics" project is a 15 state collaborative effort jointly sponsored by AHRQ, NASMD, NASMHPD, and the Medicaid Medical Directors Network (NMDN). The project, implemented in late 2008, has as its purpose a review of costs, utilization, and safety issues related to children receiving mental health medications. Data analysis covers four years, 2004 to 2007, for children 0-18 years of age enrolled in Medicaid in each year. The project's primary focus is on atypical antipsychotic (AAP) use in children; however, a broad review of mental health drugs (MHD) is included. The issue, especially for atypical antipsychotic medications, is a concern that for children, most AAP use is off label and that AAP use may lead to long-term health hazards, including the development of obesity and diabetes. Parents and child advocates nationally have voiced concerns that children are receiving too many psychotropic medications at too high a dose too young. Results from this project can be used to help define quality indicators to help assess and promote best practices. While Iowa did not participate in this project, an analysis was performed over a similar time period (2005 - 2009) with similar data parameters to examine this utilization within the Iowa Medicaid population. The number of children on typical antipsychotics did not change much between 2005 and 2009, but the percentages on atypicals did fluctuate. Generally speaking, usage went down in the younger age groups and up in those 15 to 18 years of age. The Commission decided to wait for national data for comparison before doing a focus study.

Duplicate Antihistamines: The purpose of this study was to determine the frequency of which Iowa Medicaid members are using multiple antihistamines. Regular reviews of member-specific charts have revealed a moderately high incidence of combining two or more antihistamines over an extended period of time. Although second generation antihistamines have less CNS depression than first generation antihistamines, the combination can still lead to increased CNS sedation and other anticholinergic side effects. Typically what is observed is a member is started on a first generation antihistamine or over-the-counter second generation antihistamine and uses it for a period of time, then requests use of a preferred or non-preferred second generation antihistamine, which is approved. When the second generation antihistamine that required a prior authorization is initiated, the over-the-counter product is never discontinued. An analysis of pharmacy claims was conducted between 10/1/2009 and 12/31/2009 to identify the number of unique members combining oral antihistamines for greater than or equal to 30 cumulative days. Antihistamines combined with decongestants were also included in this search. Additionally, we looked at members who combined the antihistamine nasal spray, *Astelin/Astepro* (azelastine) with oral antihistamines for greater than or equal to 30 cumulative days. One hundred eighty-

seven members continued their duplicate antihistamine regimen into December, and letters will be sent to the providers associated with these members.

Synagis Utilization in 2009-2010 RSV Season: The Commission was provided trending information over several recent years of palivizumab (*Synagis*) utilization data within the Iowa Medicaid population to determine if changes to the palivizumab (*Synagis*) coverage policy for the 2010-2011 season are necessary. Palivizumab (*Synagis*) has required a clinical prior authorization for all Iowa Medicaid members since the Preferred Drug List was implemented in January of 2005. The prior authorization criteria are based on the manufacturer labeling and the *Redbook* guidelines adopted by the American Academy of Pediatrics (prior to the 2009-2010 RSV season). Prior to the 2009-2010 RSV season, *Redbook* released updated recommendations for the use of palivizumab (*Synagis*) for the upcoming season. These updated recommendations were based primarily on updated pharmacoeconomic studies. In August of 2009, the American Academy of Pediatrics' Committee on Infectious Diseases updated their Policy Statement in support of the new *Redbook* guidelines. Following a thorough review of the new data behind the revised guidelines, the DUR Commission was opposed to adopting the full updated *Redbook* guidelines. The Commission did, however, recommend limiting the season to 5 doses beginning in November and ending in March per the new guidelines, but recommended not adopting the guideline that called for a maximum of 3 doses or dosing only until the infant reaches 90 days of age for those born from 32 weeks, 0 days' gestation through 34 weeks, 6 days' gestation who qualify for prophylaxis. It is important to note that independent of the DUR Commission's deliberations, the University of Iowa Hospitals and Clinics adopted similar guidelines for their physicians who prescribe palivizumab. For the 2009-2010 RSV season in Iowa, RSV was considered to be at epidemic levels (two consecutive weeks with two 10% positive rapid antigen RSV tests) the week ending December 26, 2009. At this point, most members who qualified for palivizumab had received two doses. While the Iowa Medicaid Enterprise adopted a hybrid of the new *Redbook* guidelines last season, of the states that responded to a survey, 21 state Medicaid programs adopted the full complement of guidelines and 6 states did not adopt the new guidelines. Overall, the feedback from those states has been positive in that there was very little push-back from the prescribers or hospitals. The Commission decided to wait for surveillance and epidemiologic data from the most recent RSV season to be made available for review before making any changes to the existing Iowa PA criteria.

Compliance with ACE, ARB, and/or Beta Blocker in CHF: The purpose of this study was to determine the rate of ACE inhibitor, beta-blocker, and/or angiotensin-receptor blocker (ARB) utilization and compliance in chronic heart failure (CHF) patients. Numerous studies have proven the benefit of ACE inhibitors and beta-blockers in patients with CHF. These products are typically initiated after the symptoms of fluid overload are addressed with loop diuretics. Current treatment guidelines from the American College of Cardiology and the American Heart Association recommend treatment with an ACE inhibitor in patients with CHF due to their favorable effect on survival. Additionally, beta-blockers are recommended for all stable patients with current or previous symptoms of heart failure and reduced left ventricular ejection fraction. It is also recommended that beta-blockers and ACE inhibitors be used in all patients with a recent or past medical history of myocardial infarction. Angiotensin II receptor blockers

are also approved for the treatment of CHF, but it is recommended that their use is reserved for those patients who are intolerant to ACE inhibitors. The goals of therapy are to improve symptoms, slow or reverse the reduction of myocardial function, and reduce mortality. An analysis was performed looking at those members with a diagnosis of CHF and their pharmacy claims histories to ensure that current guidelines were being followed with regard to prescription drug use. Members with current Iowa Medicaid eligibility were screened to identify those with ICD-9 codes in their medical claims history that correspond to a diagnosis of CHF. Non-reversed, paid pharmacy claims between 1/1/10 and 2/28/10 were analyzed. Claims for ACE inhibitors, beta-blockers, and angiotensin II receptor blockers were identified. Once these were found, a medication possession ratio was performed. 11,090 unique members were identified as having a CHF diagnosis, but only 1,205 (10.9%) of them are using an ACE inhibitor, beta-blocker, and/or an angiotensin II receptor blocker. These numbers will be rerun to identify people who have had a hospital admission or ER visit, with a primary diagnosis of CHF. Dr. Graber also recommended looking at members who've had echocardiograms. New findings will be brought back to a future meeting for analysis.

Under-Utilization of Statins in Diabetes: The purpose of this study was to determine the extent of statin utilization in patients with diabetes. After reviewing utilization patterns of cholesterol-lowering medications in patients following a new diagnosis of myocardial infarction, unstable angina, or acute coronary syndrome, there was an interest to review statin utilization in another vulnerable population. The American Diabetes Association 2010 Standards of Medical Care in Diabetes recommends statin therapy be added to lifestyle modifications for diabetic patients regardless of baseline lipid levels for those with overt cardiovascular disease (CVD), for those without CVD who are over 40 years of age and have at least one risk factor for CVD, and for those with LDL greater than 100. For those with multiple CVD risk factors, the goal LDL level is less than 100mg/dL. For patients with overt CVD, the recommended goal LDL level is less than 70mg/dL. Medicaid members with current eligibility and a new diagnosis for diabetes in 2009, who also had at least one diagnosis code for cardiovascular disease in their medical claims history that have never filled a statin, were identified. Three thousand, three hundred-six unique members with a new diagnosis of diabetes in 2009 with at least one diagnosis for CVD were identified. Twenty-seven of them were under 18 years of age, of which none have ever filled a statin. Three hundred-ninety two were between 18 and 39 years of age, of which 337 (86%) have never filled a statin; and 2,887 were 40 years of age or older, of which 2,409 (83.4%) have never filled a statin. It is extremely difficult, if not impossible, with this large of a population size to determine how many potential CVD risk factors members have. Additionally, lipid levels are not collected in data, so there is no way to determine if a diabetic patient has an LDL greater than 100 mg/dL without pharmacotherapy. Thus, this will appear as an article in an upcoming DUR Digest.

Long-Acting Beta Agonists in Asthma: The purpose of this study was to identify members using long-acting beta-agonist inhalers for the treatment of asthma, and to make prescribers aware of new warnings from the FDA. In February of 2010, the FDA released new recommendations to help improve the safe use of long-acting beta-agonist (LABA) inhalers for the treatment of asthma. This alert was in response to an analysis of studies that showed an increased risk of hospitalizations and death in adults

and children with asthma using LABA inhalers due to an increased risk of severe exacerbation of asthma symptoms. The drugs that were included in this recommendation were salmeterol (*Serevent*), formoterol (*Foradil*), fluticasone/salmeterol (*Advair*), and budesonide/formoterol (*Symbicort*). While manufacturers of LABAs are updating their package inserts and implementing strategies to reduce the overall use of these medications, we performed an analysis to determine how these products were being used in the Iowa Medicaid population. Medicaid members with current eligibility and a diagnosis of asthma in their medical claims were identified. Of these members, we reviewed non-reversed, paid pharmacy claims between 12/1/09 and 2/28/10 to identify how many members had claims for salmeterol (*Serevent*), formoterol (*Foradil*), fluticasone/salmeterol (*Advair*), and/or budesonide/formoterol (*Symbicort*). For those identified as using one of these products, we looked at how many were combining this regimen with an asthma-controller medication (corticosteroid, leukotriene, anti-inflammatory, and/or xanthine). We also looked at those under 18 years of age who were using the single ingredient products compared to the combination products. Of these 27,184 members, 1,834 (6.75%) were identified as having claims for a long-acting beta agonist between 12/1/09 and 2/28/10, of which 575 members were under the age of 18 years old; 17 of these members were found to be using duplicate LABAs. Of the 1,834 members identified as having recent claims for a long-acting beta agonist between 12/1/09 and 2/28/10, 824 (44.9%) were identified as combining the long-acting beta agonist with a "controller" medication. 1,010 (55.1%) members were identified as using a long-acting beta agonist without a "controller" medication. For those under 18 years of age, the ratio of single ingredient products to combination products was 0.08. This will appear as a DUR Digest article.

Valproate Use as Mood Stabilizer in Women of Childbearing Age: The purpose of this study was to determine the frequency of which women of childbearing age in the Iowa Medicaid population are using valproate for non-seizure diagnoses. The FDA recently published a reminder to health care professionals about the increased risk of major birth defects in infants exposed to valproate sodium and related products in utero. These birth defects can include neural tube defects, craniofacial defects, and cardiovascular malformations. Infants exposed to valproate during the first 12 weeks of a pregnancy have an increased risk of neural tube defect in 1 in 20 infants. When used to treat epilepsy, the North American Antiepileptic Drug Pregnancy Registry reports that the rate of major malformations in infants born to women with epilepsy taking valproate is nearly 4 times higher than the rate of major malformations in infants born to women taking other agents. The communication from the FDA goes on to encourage health care providers to counsel women of childbearing age about the increased risk of birth defects when valproate is taken during pregnancy, and that effective contraception should be used in women not planning a pregnancy. An analysis of pharmacy claims was conducted between 12/1/2009 and 2/28/2010 to identify the number of female members of childbearing age (aged 16 years and older) who received two or more prescriptions for any valproate product. Of those identified, we removed any member who also had claims during the same time for hormonal contraceptive products, physician administered contraceptive products, and those who had undergone surgical sterilization. We also removed any member with a seizure diagnosis. The remaining members were determined to be using valproate for a mental health or other compendia-listed indication. A sub-analysis was performed to determine how many

members also had a pregnancy diagnosis during the time valproate was used. Seven hundred-four unique female members, aged 16 years or older, received two or more prescriptions for valproate between 12/1/09 and 2/28/10. The remaining female members, aged 16 years of age or older, who are using valproate for a diagnosis other than seizure disorder who may have a higher risk of pregnancy totaled 177. Dr. Graber recommended that the data be rerun, limiting the ages to between 16 and 45, to allow for use in post-menopausal women. Letters will be sent to the prescribers of the members within this age bracket. Craig Logemann also noted that the ones using valproate for seizures should still be included in the study. Dr. Graber thought it would also be interesting to see how many women taking anti-seizure medication were also on folic acid.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 3.

SMAC Updates: The Commission members were given a copy of the SMAC changes that had gone into effect in March and April.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 11:26 to adjourn the meeting and move to closed session (first by Rick Rinehart, second by Sara Schutte-Schenck).

The next meeting will be held at 9:30 a.m. on Wednesday, June 2, 2010 at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes June 2, 2010

Attendees:

Commission Members

Bruce Alexander, R.Ph., Pharm.D., BCPP; Casey Clor, M.D.; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambrosion, R.Ph.; Rick Rinehart, M.D.; Susan Parker, Pharm.D.; and Mark Graber, M.D., FACEP.

Staff

Thomas Kline, D.O.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Chairperson Dr. Mark Graber called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. Commission members and guests were welcomed and introduced. Bruce Alexander received a letter and certificate of recognition from the Iowa Medicaid Director for his 8 years of service to the DUR Commission.

The minutes from the May 5, 2010 meeting were approved. (Motion by Larry Ambrosion, second by Dr. Rick Rinehart, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

Dr. Jason Kessler was recently named the new Iowa Medicaid Medical Director. A Clinical Advisory Committee meeting was held in May; they are currently looking for 3 new members. Beginning July 1, 2010 there will be some new programs at the IME, as well as contract integration and new vendors. Lock-in services will now be operated by Member Services instead of Medical Services. DHS is still working through how much of an impact Healthcare Reform will have on drug rebates. The SSDC pool meeting to discuss rebates for the next calendar year is June 15-16. DHS is also in the process of establishing rules for bringing mental health drugs onto the PDL. Draft rules and timeline were posted on www.iowamedicaidpdl.com under the Rules link, and emailed to the listserv as well. The next P&T Meeting will be September 9th at the Capitol. Informational letter 903 was just sent out, announcing changes brought about from the last P&T Meeting, along with new PA criteria for *Cymbalta*, *Lyrica*, and *Savella*.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$16,332.65 pre-rebate (state and federal).

Public Comment

Thomas Carattini from Accord Pharmaceuticals spoke about Ampyra. Victoria Lopez from Endo Pharmaceuticals offered to answer any questions about the Lidoderm Patch as it was on the agenda. Karen Loihl from the Iowa Psychiatric Society voiced concerns regarding the proposed prior authorization criteria for Intuniv, along with the fact that it had been referred to the Mental Health Advisory Group but no meeting had been called to discuss it. Nancy Bell congratulated Bruce Alexander on his retirement from the DUR Commission and thanked him for his service.

PA Criteria

Extended Release Formulations: The Commission reviewed the prior authorization criteria as follows:

Payment for a non-preferred extended release formulation will be considered when the following is met:

- *Previous trial with the preferred immediate release product at a therapeutic dose that resulted in a partial response with a documented intolerance to the preferred immediate release product of the same chemical entity and a*
- *Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Larry Ambroson motioned to accept the proposed criteria, and Dr. Rick Rinehart seconded. The motion passed unanimously.

Extended Release Guanfacine (Intuniv): The Commission reviewed a letter from the Iowa Psychiatric Society regarding concerns about the proposed prior authorization criteria for Intuniv. The Commission reviewed the prior authorization criteria, as follows, addressing the issues within the letter:

Prior authorization is required for Intuniv. Payment will be considered for patients when the following is met:

- 1) The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
- 2) Previous trial with immediate release guanfacine at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
- 3) Previous trial and therapy failure at a therapeutic dose with two of the following: a preferred amphetamine stimulant, a preferred non-amphetamine stimulant, or Strattera.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

A quantity limit of 30 tablets per 30 days for all strengths (1mg, 2mg, 3mg, and 4mg) was also recommended. Craig Logemann motioned to accept the criteria, and Bruce Alexander seconded. The motion passed with no objections or abstentions.

Sodium Oxybate (Xyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:

- 1. A diagnosis of cataplexy associated with narcolepsy and previous trial and therapy failure at a therapeutic dose with a tricyclic antidepressant or SSRI.*
 - 2. A diagnosis of excessive daytime sleepiness associated with narcolepsy and previous trial and therapy failure at a therapeutic dose with a preferred stimulant.*
 - 3. Requests for patients with a prior history of substance abuse will not be considered.*
- The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

This topic was tabled until a future meeting so that information and wording could be clarified regarding the stimulants, making the language consistent with other prior authorizations.

Dalfampridine (Ampyra): The Commission reviewed the prior authorization criteria as follows:

- Prior authorization is required for dalfampridine (Ampyra™).*
- Payment will be considered for patients that have a gait disorder associated with MS.*
- Initial authorizations will be approved for 12 weeks; additional prior authorizations will be considered after assessing the benefit to the patient as measured by an increase in walking speed using the Timed 25-foot Walk assessment.*
- Prior authorizations will not be considered for patients with a seizure diagnosis or in patients with moderate or severe renal impairment.*

A quantity limit of 60 tablets per 30 days was also recommended. Neurologists will be contacted for feedback, and their input will be brought back to the next meeting.

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis. Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: sulfasalazine and methotrexate.

Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

Dr. Casey Clor motioned to accept the modified criteria, and Bruce Alexander seconded. The motion passed unanimously.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for rheumatoid arthritis. Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline, and a combination of methotrexate and another preferred disease modifying antirheumatic drug (DMARD) unless contraindicated.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

This will be brought back to the next meeting with updated wording.

Biologicals for Inflammatory Bowel Disease: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for inflammatory bowel disease. Prior authorization is required for all non-preferred biologicals for inflammatory bowel disease as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred biologicals for Crohn's disease will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred agents.

- *Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies such as aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.*
- *Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies such as aminosalicylates, and/or azathioprine/6-mercaptopurine.*

Dr. Mark Graber motioned to accept the proposed criteria, and Dr. Casey Clor seconded. There were no objections.

Biologicals for Plaque Psoriasis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for plaque psoriasis. Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. Prior authorization is required for all non-

preferred biologicals for plaque psoriasis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred agents.

Dr. Casey Clor motioned to accept the proposed criteria, and Larry Ambrosion seconded. There were no objections.

Lidocaine Patch: At the April 8, 2010 P&T Committee meeting, it was requested the DUR review the language for the Lidocaine Patch PA. It was the P&T Committee's opinion that the language was restrictive and gave the impression that it would only be approved for a diagnosis of pain associated with post-herpetic neuralgia. The Prior Authorization Criteria chart, available online, states at the top of each page "The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber on the request for prior authorization form, including dates, dose, and nature of failure." All PA Criteria follows the same format listing only FDA approved indications. The only FDA approved indication for *Lidoderm* is post-herpetic neuralgia. The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for topical lidocaine patches (Lidoderm®). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with two preferred agents at a therapeutic dose from two of the following: tricyclic antidepressant, opioid, gabapentin, carbamazepine, or valproic acid. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

Larry Ambrosion motioned to accept the proposed criteria, and Dr. Casey Clor seconded. The decision was unanimous.

Pro-DUR Edits

Quetiapine (Seroquel): Through the process of reviewing regular member profiles, it has been observed that members are receiving multiple tablets of the same strength of quetiapine (*Seroquel*) where there is the potential to consolidate the dose to a higher strength tablet, thus resulting in a cost savings to the State. Quetiapine (*Seroquel*) is the only atypical antipsychotic not subject to quantity limits. Quetiapine (*Seroquel*) is indicated for the treatment of schizophrenia and bipolar disorder. Recommended dosing is either twice to three times daily, depending on the diagnosis, with a maximum dose of 800mg per day. It has also been observed that members are taking low doses of quetiapine (*Seroquel*) without a valid diagnosis in their medical claims history. Non-reversed, paid pharmacy claims were analyzed between 3/1/10 and 4/15/10 looking at the number of tablets per day of quetiapine (*Seroquel*). In addition, members using low dose quetiapine (*Seroquel*) without any other strengths of quetiapine (*Seroquel*) in their

pharmacy claims history were identified. Based on the findings, Dr. Richard Rinehart motioned to adopt the proposed quantity limits and Craig Logemann seconded. All were in favor of this decision. No Pro-DUR edits blocking low dose *Seroquel* will be developed at this time, although this issue may be re-evaluated in January.

Public Comment

There were no speakers in this public comment section.

Focus Studies

Dronabinol (Marinol) Utilization: The purpose of this study was to determine the frequency of off-label dronabinol (*Marinol*) utilization. Dronabinol (*Marinol*) is a synthetic form of delta-9 tetrahydrocannabinol (THC), the active chemical entity in marijuana. It was first approved by the FDA in 1985 and is indicated for the prevention of chemo-induced nausea and vomiting that has been refractory to other antiemetic treatments, as well as anorexia associated with weight loss in AIDS patients. While dronabinol (*Marinol*) has not had a high amount of utilization in the Iowa Medicaid population, its use remains steady when comparing quarters over the last few years. During the first quarter of calendar year 2010, forty-seven prescriptions were filled for 24 unique members with a total paid amount of \$51,044.05 (pre-rebate; state and federal dollars). It has been suspected, through the review of member profiles, that some of this utilization has been for off-label use. Non-reversed, paid pharmacy claims were analyzed between 1/1/10 and 3/31/10. Members with claims for dronabinol (*Marinol*) during this time were identified. The medical claims histories for those members who had claims for dronabinol (*Marinol*) were then analyzed. Of the 12 members who did not have an approved indication in their claim histories, the top 3 most commonly observed ICD-9 codes associated with dronabinol (*Marinol*) use were: malaise and fatigue, lumbago, and pain in limb. A focus study will be developed to contact the prescribers of those members who were identified as using dronabinol (*Marinol*) for what appears to be an off-label use. This issue will also be referred to the P&T Committee with the recommendation to make dronabinol (*Marinol*) non-preferred.

Quetiapine Off-Label Utilization: The purpose of this study was to determine the frequency of off label quetiapine (*Seroquel*) utilization, particularly for the treatment of ADD/ADHD. Through the process of reviewing regular member profiles and monitoring prior authorization requests, the use of quetiapine (*Seroquel*) for off label indications appears to remain high, particularly for the treatment of ADD/ADHD in children and adolescents. Quetiapine (*Seroquel*) was first approved in 1997 and is indicated for the treatment of bipolar disorder, schizophrenia, and as adjunctive therapy for major depressive disorder. The immediate release product is a preferred product on the Iowa Medicaid Preferred Drug List, while the extended release version is non-preferred and requires a prior authorization. Neither formulation is subject to quantity limit edits. The two most common off label uses observed through the PA department are low dose quetiapine (*Seroquel*) for sleep and for children and adolescents for ADD/ADHD. Quetiapine (*Seroquel*) does not have a listing for ADD/ADHD in the compendia as there

is no good data to support its use for the treatment of ADD/ADHD. Non-reversed, paid pharmacy claims from 1/1/10 to 3/31/10 were analyzed. Members who had paid claims for quetiapine (*Seroquel*) during this time were identified. We then reviewed the medical claims histories of those identified as having fills for quetiapine (*Seroquel*). There were 3,243 members with claims for quetiapine (*Seroquel*) between 1/1/10 and 3/31/10, with 1,756 members without an approved diagnosis for use (bipolar disorder, schizophrenia, or depression), including 660 members with a diagnosis of ADHD without a co-existing approved diagnosis. This issue was referred to the Mental Health Advisory Group for further evaluation and additional suggestions to discourage off-label usage.

Duplicate Long-Acting Stimulants: The purpose of this study was to determine the frequency of concurrent use of long acting stimulants. Through the process of regular member profile reviews, the combination of long acting stimulants is frequently observed. Stimulants do not require a PA in members less than 21 years of age, which is where the majority of these duplications occur. For those 21 years of age and older, a prior authorization is required. When prior authorizations are requested for duplicate long acting stimulants, they are denied without proper medical rationale as to why the combination is warranted (most are for severe narcoleptic patients who have failed to control symptoms with a single agent). Using duplicate long acting stimulants can have an additive effect, increasing the risks of tachycardia, hypertension, and other noradrenergic side effects. Additionally, it is more costly to use two products at sub-therapeutic doses when symptoms could be controlled on one agent at a full, therapeutic dose. Available treatment guidelines for ADD/ADHD do not support the use of duplicate long acting stimulants. Non-reversed, paid pharmacy claims were analyzed between 12/1/09 and 3/31/10. Members who were using duplicate long acting stimulants concurrently for two or more months that continued the combination into March 2010 were identified. These members were broken out to those over 21 years of age, and those 21 years of age and under. 170 members continued the combination of long-acting stimulants into March 2010, 165 of them 21 years of age or younger. This was also referred to the Mental Health Advisory Group. The members asked that the number of prescribers for each member and their respective specialties be added to the report.

Multiple Anti-Epileptic Medications: The purpose of this study was to determine the number of Iowa Medicaid members using three or more anticonvulsants for any diagnosis concurrently. It is often noted in member profile reviews that members are on multiple anticonvulsants concurrently. This often receives comments on the member profiles discussed at Commission meetings. Anticonvulsants can be prescribed for the treatment of seizure disorders or for the maintenance of bipolar disorder. When used as maintenance therapy for bipolar disorder, the American Psychiatric Association's Practice Guideline for the Treatment for Patients with Bipolar Disorder recommends the use of lithium as first line therapy followed by valproic acid if lithium is not tolerated or does not produce a response. Lamotrigine and carbamazepine are considered possible

alternatives if a second medication is required. When used to treat epilepsy, approximately half of the patients with a new diagnosis of epilepsy are successfully treated with the first antiepileptic used. If a trial with a second product is required, either due to an inadequate response or side effects, nearly half of these patients will be successful with the second drug. Combination and polypharmacy is only recommended if at least two adequate trials of single agents have failed. It is estimated that only 10-15% of patients achieve seizure remission with two or more products in combination following failure of monotherapy. Another recent phenomenon observed in the Pharmacy Prior Authorization department is an increase in the use of the new antiepileptic drug, *Banzel* (rufinamide). *Banzel* (rufinamide) is FDA-approved for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome. Many of the prior authorization requests that have been received are requesting *Banzel* (rufinamide) for an off-label indication (the efficacy of *Banzel* in treating other seizure types has not been established) and/or it is being requested as an addition to an existing antiepileptic regimen as a fourth or even fifth product. The use of *Banzel* (rufinamide) has slowly increased in the Iowa Medicaid population; in the first quarter of calendar year 2010, there were 121 prescriptions filled for a total cost of \$39,090 (state and federal dollars, pre-rebate). Non-reversed, paid pharmacy claims were analyzed between 1/1/10 and 3/31/10. Members with two or more prescriptions in their claims history for any anticonvulsant were identified (clonazepam and diazepam were not counted as anticonvulsants for this report). Of those identified, those who were using three or more different anticonvulsants concurrently were identified and analyzed. Of the 334 members taking three or more different anticonvulsants concurrently, 27 were identified as having *Banzel* (rufinamide) as part of their regimen. Letters will be sent to the prescribers of *Banzel* to inquire about the diagnosis for use since it is only FDA approved for use in Lennox-Gastaut syndrome and cannot be teased out by looking at ICD-9 codes. Letters will also be sent to the prescribers of the members who had a diagnosis of bipolar disorder or conversion disorder without a coexisting seizure diagnosis who were not on any combinations of carbamazepine, valproate, and lamotrigine. Nineteen members identified as using 3 or more anticonvulsants concurrently without a corresponding diagnosis of epilepsy or bipolar disorder will also receive letters. Letters will also be sent to the prescribers of the members being treated with three or more anticonvulsants with a diagnosis of febril convulsions if they do not have any other seizure diagnosis.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 3.

SMAC Updates: The Commission members were given a copy of the SMAC changes that had gone into effect in May.

MedWatch: The Commission members received FDA announcements concerning new

Black Box Warnings.

A unanimous vote was made at 12:10 p.m. to adjourn the meeting and move to closed session (1st by Bruce Alexander, 2nd by Dr. Richard Rinehart).

The next meeting will be held at 9:30 a.m. on Wednesday, August 4, 2010 at the Learning Resource Center in West Des Moines.

Appendix N

Mental Health Work Group

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG), formerly known as the Mental Health Work Group, was established in State FYE 2008. It is currently comprised of three members of the Drug Utilization Review Commission (one pediatrician, one psychiatrist, and one psychiatric pharmacist), several pediatric and adolescent psychiatrists, an adult psychiatrist, and a psychiatrist from Magellan Health Services.

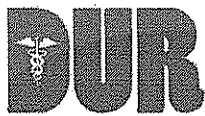
The Mental Health Advisory Group is a separate entity from the Iowa Medicaid Drug Utilization Review (DUR) Commission. All recommendations from the MHAG must be approved by the DUR Commission before they can be implemented.

The original goal of the MHWG was to address issues that developed specific to the pediatric and adolescent psychiatrists within the State of Iowa when mental health drug consolidation edits were implemented in October, 2007. Since then, the DUR Commission has made the decision to refer other mental health issues that impact the entire mental health population of Iowa Medicaid, regardless of the members' age.

The MHAG met once in State FYE 2010. The minutes from the July meeting have not been approved by the members of the MHAG and therefore are not included in this report.

Appendix O

Smoking Cessation Report



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.

DUR Project Coordinator

Chad Bissell, Pharm.D.

To: Susan Parker, R.Ph., Pharm.D.

From: The Iowa Medicaid Drug Utilization Review Commission

Regarding: The Iowa Medicaid Smoking Cessation Program

Date: February 5, 2010

Enclosed please find copies of reports to the Department relative to the Iowa Medicaid Smoking Cessation Program.

This report is divided into three sections: Background, Program Results, and DUR Review and Recommendations.

Background

A. Program Review

- The 2005-2006 General Assembly passed HF825 and HF841 requesting that the Department expand coverage under the medical assistance program to cover smoking cessation drugs. This was to be done in collaboration with the Iowa Department of Public Health programs relating to tobacco use prevention and cessation.
- Iowa Medicaid requested that the Iowa Medicaid Drug Utilization Review (DUR) Commission develop prior authorization criteria for the smoking cessation program incorporating counseling through Quitline Iowa. (Studies have shown that smoking cessation programs that incorporate counseling in conjunction with medication therapy have higher success rates.)
- The Pharmaceutical and Therapeutics (P&T) Committee were requested to review the smoking cessation products for inclusion on the Preferred Drug List.
- Effective January 1, 2007, the Iowa Medicaid Program expanded coverage to include select over-the-counter nicotine replacement patches and gum, and generic bupropion sustained-release (SR) products that are FDA-indicated for smoking cessation (generic Zyban®). Bupropion 150mg sustained-release products that are FDA-indicated for smoking cessation (generic Zyban®) are available without prior authorization (PA). Over-the-counter nicotine replacement patches and gum are covered with a prior authorization.

- The Iowa Medicaid DUR Commission reviewed the clinical information available for varenicline (Chantix™) on several occasions and had recommended to the Department of Human Services the drug not be covered until more safety and efficacy data were made available. Specifically, the Commission was interested in seeing safety and efficacy data on varenicline (Chantix™) used in medically complex patients with multiple chronic conditions that more closely resembled the Medicaid population. To date, such data is not available. The Department of Human Services made the decision, however, to provide coverage of varenicline (Chantix™) since safety and efficacy had already been proven as part of the Food and Drug Administration's (FDA) approval process. Therefore, effective February 18, 2008, the Iowa Medicaid Program again expanded coverage to include the prescription product, varenicline (Chantix™) with a prior authorization.

B. Prior Authorization (PA) Criteria for Nicotine Replacement Therapy and Varenicline (Chantix™)

Following recommendations from both the DUR and P&T Committees, the prior authorization criterion were established as follows:

Prior Authorization is required for over-the-counter nicotine replacement patches and nicotine gum. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment in the Quitline Iowa counseling program is required for approval.
- 3) Approvals will only be granted for patients eighteen years of age and older.
- 4) The maximum allowed duration of therapy is twelve weeks within a twelve-month period.
- 5) A maximum quantity of 14 nicotine replacement patches and/or 110 pieces of nicotine gum may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4-week supply at one unit per day of nicotine replacement patches and/or 330 pieces of nicotine gum. Following the first 28 days of therapy, continuation is available only with documentation of ongoing participation in the Quitline Iowa program.
- 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation

Prior Authorization is required for varenicline (Chantix™). Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.
- 3) Approvals will only be granted for patients eighteen years of age and older.

- 4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.
- 5) Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.
- 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation

C. Prior Authorization (PA) Process

- Iowa Medicaid members who want assistance in quitting smoking need to be referred to Quitline Iowa by their healthcare provider.
- If it is determined that the member would benefit from using over-the-counter nicotine replacement patches and/or gum, a Nicotine Replacement Therapy Prior Authorization form must be completed by the member and the prescriber. Alternatively, if it is determined that the member would benefit from using varenicline (Chantix™), a Varenicline (Chantix™) Prior Authorization form must be completed by the member and the prescriber. The completed form(s) is then faxed to Quitline Iowa. Quitline Iowa will follow up with the member and assess the member's smoking cessation counseling needs.
- Following this initial consultation, Quitline Iowa will submit the prior authorization request to the Iowa Medicaid Pharmacy Prior Authorization Unit for coverage of the necessary smoking cessation products.
- In the event that the member chooses to disenroll from the Quitline Iowa program, all approved prior authorizations will be cancelled and notification will be faxed to the provider and pharmacy, while a letter will be mailed to the member.

Program Results

Quitline Program

National Jewish Medical and Research Center began providing Quitline services for the Iowa Department of Public Health (IDPH) on January 1, 2008. The University of Northern Iowa has partnered with National Jewish to evaluate participant satisfaction and quit rates. The relationship between Iowa Medicaid and IDPH is a collaborative effort to provide smoking cessation products through Medicaid and counseling services through IDPH (via the contractual relationship with National Jewish Medical Center) to those who qualify for Iowa Medicaid.

Current literature for all populations, not solely Medicaid members, that examine quit rates for various interventions reports that the odds ratio of maintaining abstinence from smoking at six months following multiple proactive call back counseling sessions after contact was initiated by a motivated quitter (similar to how the Quitline Iowa program works) is 1.41.¹ It has also been found that higher intensity

¹ Meites, Elissa. Telephone Counseling Improves Smoking Cessation Rates. *Am Fam Physician*. 2007; 75(5): 650.

disease management is associated with higher abstinence from smoking.² When smoking cessation counseling is combined with drug therapy, the odds of achieving cessation are often times doubled.

When looking at the odds ratio of maintaining abstinence from smoking six months after using pharmacotherapy, current literature (not exclusively looking at a Medicaid population) report the following: nicotine patches – 1.81; nicotine gum – 1.66; bupropion – 2.06. When compared to varenicline (Chantix™), the odds ratio of maintaining abstinence from smoking after 12 weeks of therapy ranges from 2.70 to 5.50.³ Currently, the only statistic available for the Chantix™ odds ratio is 12 weeks.

Quitline Iowa received 5,473 faxed referrals for Iowa Medicaid members between October 1, 2008 and September 30, 2009. From these referrals, 3,339 members were enrolled in the Quitline program. During the same time frame, 1,663 members were disenrolled from the Quitline program. The inability to reach the member was a barrier to the enrollment process as Quitline counselors often received constant busy signals, invalid phone numbers, or disconnected phones. For the specified time period above, 1,659 (30%) members could not be reached by the Quitline counselors, 222 (4%) members declined enrollment, and 253 (5%) members requested information only. Compared to data from last year, 1,418 (27%) members could not be reached by the Quitline counselors, 201 (4%) members declined enrollment, and 241 (5%) members requested information only. It should be noted, data from last year was only for a nine month time frame.

The University of Northern Iowa is responsible for completing follow-up interviews with Iowa Medicaid members who participated in the Quitline Iowa counseling program. Interviews assess whether the participant has “quit smoking”, which is defined as not having had a cigarette in the 30 days prior to the follow-up interview. Three groups of members are interviewed by the University of Northern Iowa: one at 3 months following their first call to Quitline, one at 6 months, and one at 12 months from a random sample of Medicaid members. Numbers reported are not unique members.

Overall, 4,426 people completed follow-up interviews. Of those 4,426 participants, 888 were classified as being Medicaid clients of Quitline. Of these 888 participants:

- 868 (99.2%) said they smoked cigarettes around the time of their first call to Quitline
- Of these 868 participants, 185 (21.1%) quit smoking
- 195 participants (23.6%) said they spoke with a Quitline representative 8 or more times.
 - Of these 195 participants, 50 (25.8%) quit smoking

In the 3-month cohort of the follow-up evaluation, 377 participants were classified as being Medicaid clients of Quitline. Of these 377 participants:

- 367 (98.9%) participants said they smoked cigarettes around the time of their first call to Quitline
 - Of these 367 participants, 86 (23.3%) quit smoking
- 68 participants (18.9%) said they spoke with a Quitline representative 8 or more times
 - Of these 68 participants, 22 (32.8%) quit smoking

In the 6-month cohort of the follow-up evaluation, 292 participants were classified as being Medicaid clients of Quitline. Of these 292 participants:

² Ellerbeck EF, Mahnken JD, Cuperjino AP et al. Effect of varying levels of disease management on smoking cessation : a randomized trial. *Ann Intern Med.* 2009;150(7):437-46

³ Nides, M. Update on Pharmacologic Options for Smoking Cessation Treatment. *Am J Medicine.* 2008; 121(4 suppl 1): S20-31.

- 287 (99.3%) participants said they smoked cigarettes around the time of their first call to Quitline
 - Of these 287 participants, 55 (19.0%) quit smoking
- 72 participants (26.9%) said they spoke with a Quitline representative 8 or more times
 - Of these 72 participants, 14 (19.4%) quit smoking

In the 12-month cohort of the follow-up evaluation, 219 participants were classified as being Medicaid clients of Quitline. Of these 219 participants:

- 214 (99.5%) participants said they smoked cigarettes around the time of their first call to Quitline
 - Of these 214 participants, 44 (20.3%) quit smoking
- 55 participants (27.6%) said they spoke with a Quitline representative 8 or more times
 - Of these 55 participants, 14 (25.5%) quit smoking

The mean number of contacts in the Quitline program for all Medicaid members who enrolled was five.

Prior Authorization Program

For the time period of October 1, 2008 through September 30, 2009, 6,852 Prior Authorizations (PA) were approved for smoking cessation products out of a total of 9,207 requests or 74% were approved. Reasons for denial of the PA include: the member was under 18 years of age, the member was not enrolled in Quitline, the PA request form was incomplete, the PA request was for a Medicare covered product for a dual eligible, or the member had disenrolled from Quitline. There were also 12 PA requests for noncovered products; two of which resulted in requests for an Exception to Policy which were not granted.

For this time period of October 1, 2008 through September 30, 2009, members received a total of 5,682 prescriptions for smoking cessation products at a total cost (federal and state dollars before rebates) of \$512,403. Administration of the pharmacy prior authorization component of the smoking cessation program during this timeframe was \$102,083 total dollars (federal and state). Any additional costs for administration of the Quitline Iowa program would be incurred by the Iowa Department of Public Health.

	Number of Prescriptions	Number of PAs Approved	Amount Paid
Bupropion	112	N/A	\$7,056
Nicotine Replacement Therapy	2,263	2,625/ 3,278 (80%)	\$103,144
Chantix	3,307	4,227/5,929 (71%)	\$402,203
Total	5,682	6,852/9,207 (74%)	\$512,403

DUR Review and Recommendations

The Commission continues to evaluate the safety and efficacy data that becomes available for varenicline (Chantix™). At their meeting held in September 2008, the Commission reviewed new safety information relative to use of varenicline in various mental health disorders. The clinical prior authorization criteria were reviewed and compared to the Veteran's Administration prior authorization criteria. The Commission came to the consensus that no recommended changes to the Medicaid clinical prior authorization criteria were required at this time. Also, the DUR Commission elected not to review the clinical PA criteria as part of the annual review of criterion during their meeting in August 2009. However, the Commission will

continue to monitor safety data and other third party payers' prior authorization criteria to determine if any changes would be appropriate in the future.

The Commission also reviewed the November 6, 2009 MMWR article *State Medicaid Coverage for Tobacco-Dependence Treatments – United States, 2007* at their meeting in December 2009. Although the article recommends open access to tobacco-dependence treatments without barriers or limitations in Medicaid populations, the Commission felt it was not appropriate for Iowa Medicaid to change the current smoking cessation program due to the low rate of requests for non-covered products and there have been no requests for use of smoking cessation therapy beyond the time limits currently in place.

The Commission recommends that Quitline continue to establish ways to collect better efficacy data on the program and specific product efficacy and utilization data including adverse drug reactions from covered medications specific to the Iowa Medicaid population. In addition, the Commission recommends that Quitline continue to develop strategies to identify and resolve communication barriers with Iowa Medicaid enrollees. At this time, the Commission has no recommended changes on the products currently covered under the smoking cessation program.

The Iowa Medicaid DUR Commission appreciates the opportunity to make these recommendations to the Department.

Bruce Alexander, R.Ph., Pharm.D., BCPP

Larry Ambrosion, R.Ph.

Mark Graber, M.D., FACEP

Laurie Pestel, R.Ph., Pharm.D.

Casey Clor, M.D.

Richard Rinehart, M.D.

Craig Logemann, R.Ph., Pharm.D., BCPS

Sara Schutte-Schenck, D.O., FAAP

Attachments (3)

Appendix P

Recommendations to the P&T

Periodically the Commission makes recommendations to the Iowa Medicaid Pharmacy & Therapeutics Committee regarding the status of a medication on the Preferred Drug List (PDL).



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.

DUR Project Coordinator

Chad Bissell, Pharm.D.

Date: September 3, 2009

To: Susan Parker, R.Ph., Pharm.D

From: Pamela Smith, R.Ph.,

RE: DUR Commission Referral to the P&T Committee

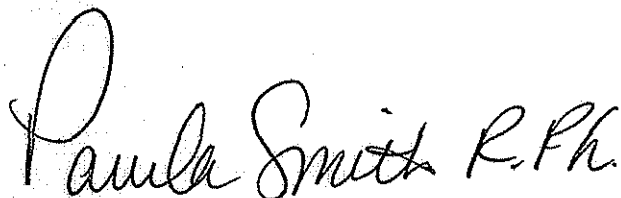
Dear Susan:

At the request of the DUR Commission members, I am forwarding the following referral to the P&T Committee members for consideration.

Ophthalmic fluoroquinolones were reviewed by the DUR Commission at their September 2nd, 2009 meeting. The American Academy of Ophthalmology guidelines on treating bacterial conjunctivitis state that "The choice of antibiotic is usually empirical. Since a 5-to-7-day course of a broad-spectrum topical antibiotic is usually effective, the most convenient or least expensive option can be selected." The recommended first line treatment options for bacterial conjunctivitis include erythromycin ophthalmic ointment (particularly for children), sulfacetamide ophthalmic drops, or polymyxin/trimethoprim drops. Most common organisms responsible for bacterial conjunctivitis respond to these agents within one to two days with a marked decrease in discharge, irritation, and redness. Alternative treatments include bacitracin ointment, sulfacetamide ointment, polymyxin/bacitracin ointment, fluoroquinolone drops or azithromycin drops. Due to the considerable cost difference between the recommended first line therapy ophthalmic antibiotics, fluoroquinolone drops, and azithromycin drops, it would be most cost effective to initiate therapy with a preferred first line therapy ophthalmic antibiotic drop or ointment. It would be desirable to shift prescribing practices away from fluoroquinolone drops to preferred first line therapy ophthalmic antibiotics. Nearly 95% of all ophthalmic fluoroquinolone drop users during a three month timeframe were using it as a first line agent, with only a handful of members having a corresponding diagnosis that would support its use as a first line agent. The DUR Commission, therefore, requests that the P&T Committee consider making all ophthalmic fluoroquinolones non-preferred on the Preferred Drug List, to shift utilization towards less expensive, first-line treatment options when treating bacterial conjunctivitis.

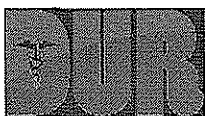
Thank you in advance for consideration of moving ophthalmic fluoroquinolone products to non-preferred status on the Preferred Drug List.

Sincerely,

A handwritten signature in cursive script that reads "Paula Smith R.Ph.".

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME
Erin Halverson, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 725-1287 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosio, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

Date: December 3, 2009

To: Susan Parker, R.Ph., Pharm.D

From: Pamela Smith, R.Ph.,

RE: DUR Commission Referral to the P&T Committee

Dear Susan:

At the request of the DUR Commission members, I am forwarding the following referral to the P&T Committee members for further consideration.

Ophthalmic fluoroquinolones were reviewed by the DUR Commission at their September 2, 2009 meeting. The DUR Commission requested that the P&T Committee consider making all ophthalmic fluoroquinolones non-preferred on the Preferred Drug List, to shift utilization towards less expensive, first-line treatment options when treating bacterial conjunctivitis. In a letter to the Department dated November 13, 2009, the P&T Committee recommended changing the status of brand ophthalmic fluoroquinolone products to non-preferred for members less than 18 years of age.

This recommendation was discussed at the December 2, 2009 DUR meeting. The DUR Commission requests the P&T reconsider their recommendation to include all ophthalmic fluoroquinolone products as non-preferred on the Preferred Drug List for members less than 18 years of age.

Thank you in advance for consideration of moving all ophthalmic fluoroquinolone products to non-preferred status on the Preferred Drug List.

Sincerely,

Paula Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Eileen Creager, IME
Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 • (515) 974-3131 • Fax 1-866-626-0216

Bruce Alexander, R.Ph., Pharm.D., BCPP
Larry Ambrosion, R.Ph.
Casey Clor, M.D.

Mark Graber, M.D., FACEP
Craig Logemann, R.Ph., Pharm.D., BCPS
Susan Parker, R.Ph., Pharm.D.

Laurie Pestel, R.Ph., Pharm.D.
Richard Rinehart, M.D.
Sara Schutte-Schenck, D.O., FAAP

Professional Staff:

Thomas Kline, D.O.

Pam Smith, R.Ph.
DUR Project Coordinator

Chad Bissell, Pharm.D.

June 2, 2010

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, June 2, 2010. At this meeting, the DUR Commission members reviewed utilization data on dronabinol (*Marinol*) for off-label use. While dronabinol (*Marinol*) has not had a high amount of utilization in the Iowa Medicaid population, its use remains steady. During the first quarter of calendar year 2010, forty-seven prescriptions were filled for twenty-four unique members. Of the twenty-four members, twelve were found to not have a corresponding diagnosis in their medical claims histories for use of dronabinol (*Marinol*). The DUR Commission recommended referring dronabinol (*Marinol*) to the P&T Committee to make it non-preferred on the Preferred Drug List.

Sincerely,

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Andi Dykstra, IME
Thomas Kline, D.O., IME
Sandy Pranger, R.Ph., IME